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GATEKEEPER

D8.4 Standardization report and recommendations

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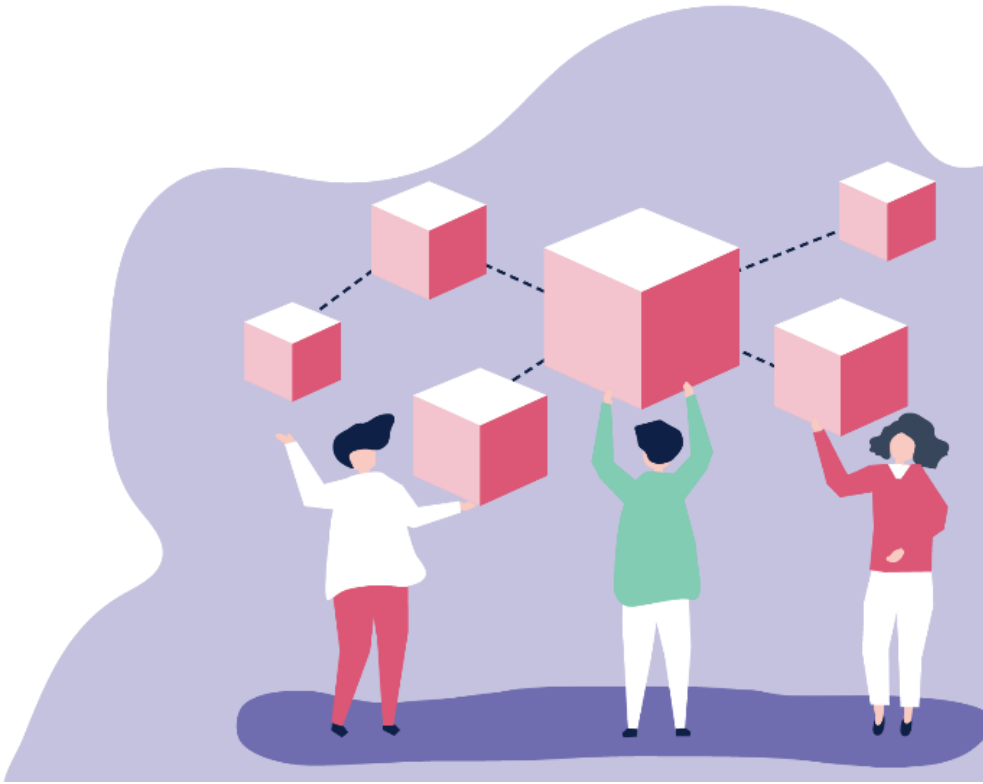

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30/09/2022	0.5	Integration of additional inputs (MDT, UPM)
30/09/2023	0.6	Integration of updates
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Abstract

This deliverable provides and overview of the standardisation framework and the standardisation activities in the Gatekeeper project. It provides a detailed overview of the project methodology, including the creation of guidelines and templates, presents the standardisation contributions developed in the project, as a result, and describes the monitoring activities ensuring progress to complete T8.2.

Statement of originality

This deliverable contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation or both.

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1 Introduction

The Standardisation report and recommendations provides an overview of the standardisation framework and the standardisation activities carried out during the project, notably the development of standardisation contributions.

In its first part, the report presents concisely how the international standardisation system is reflected at EU level, and their links to national standardisation. The report extends on the methodology used for the approach to standardisation in the Gatekeeper project, developed to work within this international framework; describing the steps of collecting stakeholder input, designing a standardisation strategy and roadmap, setting up templates and creating standardisation contributions.

A number of potential topics for standardisation were identified early on in the project, which resulted in a selection of specific contributions made by project partners (some individually, other jointly, by groups of partners) and to various standardisation organisations. These contributions are described in detail this report, and cover a number of areas, for example:

- protection of personal data
- data representation
- clearing for data exchange
- intervention process modelling
- telemonitoring data and profiles
- FHIR (Fast Healthcare Interoperability Resources) certification.

As a unique way to support other research projects with the aim of contributing to standardisation efforts as part of their objectives, the deliverable also provides templates and guidelines on how to provide standardisation contributions at global, regional and national levels.

Finally, the report provides an overview of the T8.2 KPIs used to monitor the standardisation activities.

2 Standardisation ecosystem in the EU

At international level, ISO (International Organization for Standardization), IEC (International Electrotechnical Commission) and ITU (International Telecommunication Union), develop, maintain, and promote standards across different industries.

- ISO develops and publishes international standards across various industries and sectors.
- IEC focuses on international standardization in the field of electrotechnology, covering electrical, electronic, and related technologies.
- ITU is a specialized United Nations agency that focuses on information and communication technologies (ICTs), including telecommunications.

European standardization organizations (CEN, CENELEC and ETSI) actively engage with ISO, IEC and ITU to ensure that European interests and perspectives are considered in the development of global standards. This collaboration helps harmonize standards and promote interoperability on a global scale.

- CEN (European Committee for Standardization): provides a platform for the development of European Standards and other technical documents in relation to various kinds of products, materials, services and processes. CEN supports standardization activities in relation to a wide range of fields and sectors including: air and space, chemicals, construction, consumer products, defence and security, energy, the environment, food and feed, health and safety, healthcare, ICT, machinery, materials, pressure equipment, services, smart living, transport and packaging.
- CENELEC (French: Comité Européen de Normalisation Électrotechnique; English: European Committee for Electrotechnical Standardization) is responsible for European standardization in the area of electrical engineering.
- ETSI (European Telecommunications Standards Institute): ETSI, is an independent, not-for-profit, standardization organization in the field of information and communications. ETSI supports the development and testing of global technical standards for ICT-enabled systems, applications and services.

In ISO and IEC, members are National Standards Organisations, whereas ITU has both member states and companies among their membership. Each European country typically has a national standardization body responsible for representing its interests in the development of European and international standards. These bodies often adopt European Standards as national standards.

EFTA countries (Norway, Iceland, Liechtenstein, Switzerland) also participate in European standardization activities. They may adopt European Standards to facilitate trade and interoperability. The European Commission plays a coordinating role in standardization activities. It can mandate certain standards through European Union Directives, especially for areas related to health, safety, and the environment.

In the EU, standards are voluntary. They do, however, achieve legal relevance when harmonised and published in the Official Journal of the EU or referenced in domestic laws and provisions. Publication of these harmonised standards triggers "presumption of conformity". When meeting the standard, compliance with the law and directives can be assumed.

Figure 1 Levels of standardisation

3 Overview of the methodology for the Gatekeeper approach to standardisation

This section provides an overview of the methodology used during the project's approach to standardisation, building on the information provided in D8.2 and highlighting the additional tasks that have been carried out to increase the quality and reach of the work.

3.1 Recap Initial Standardisation Strategy (D8.2)

In the context of T8.2 GATEKEEPER platform standardization process and wide-spread adoption across Europe, the objective of D8.2 was to deliver a standardisation strategy to be adopted by the GATEKEEPER consortium. It was intended to be a synthetic report that can be adapted and updated in the future following the technological developments of the project, as well as the discussions between partners and any complementary inputs from research partners.

As the execution of the standardisation strategy, and in a broader term, the success of T8.2 is dependent on the developments of technological innovations, D8.2 focused on studying the potential for standardisation and suggested a coherent standardisation plan. The overall standardisation approach and process is depicted on Figure 2.

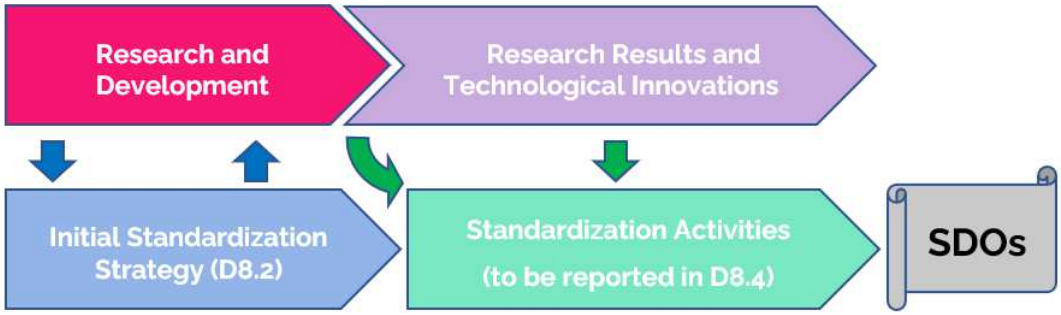

Figure 2 Standardisation processes interdependencies and sequence

The methodology if D8.2 followed a 7-step process, as shown in the figure below:

Figure 3 Overall methodology and strategy for standardisation design approach

Based on the results of the internal standardisation survey (as further explained in Section 3.2), as well as D8.2 itself, the following table summarises the key takeaways of the actions undertaken:

Table 1 Key takeaways of D8.2

KPI and Targets	
KPI	**Target**
Number of contributions to SDOs	10
Percentage of joint contributions	50%
Percentage of identified innovations brought to standardisation succeeding to be taken into account in draft standards	50%

Standardisation domains			
WHAT	**WHO**		**WHERE**
	Lead contributors	Lead SDO facilitator	
GATEKEEPER architecture	CERTH, ENG	FUNKA	CEN
		ERCIM	AIOTI
		MI	ITU
Interoperability enablers	ERCIM, MYS, HL7, HPE, ENG, CERTH, MUL, OU, UPM	MI	ITU
			ISO
		FUNKA	CEN
FHIR implementation guides	HL7, ERCIM, MYS, UPM	HL7	HL7

WHAT	WHO		WHERE
	Lead contributors	Lead SDO facilitator	
Web of Things	ERCIM, UPM, CERTH	ERCIM, UPM, HL7 Europe	W3C
Data protection, security and GDPR compliance	UDGA	MI, UDGA	ECCP
		HL7	ISO
		MI	ITU
		ERCIM	ETSI
		FUNKA	CEN
		HL7	HL7

3.2 Internal survey and review of the Gatekeeper potential for standardisation

A survey was distributed within the GATEKEEPER consortium to capture potential research results for standardisation. The survey was structured around the three Ws questions, as illustrated below:

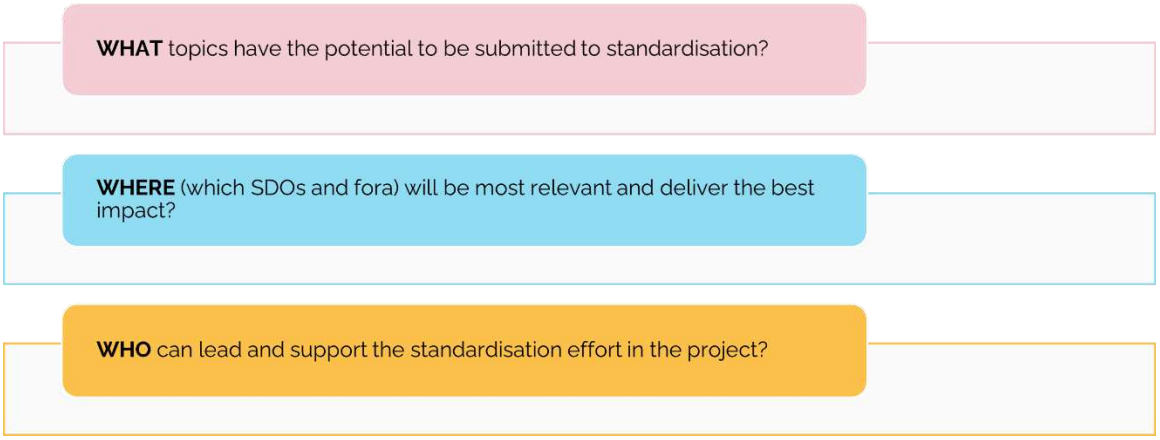

Figure 4 The three Ws questions

As shown in Appendix A of D8.2, both closed and open questions were included about future standardisation efforts and exploitation plans. The 'Partner perspective' section (Section A) discussed exploitable results from GATEKEEPER, value propositions, intellectual property strategy, and possible partnerships. Section B, 'Partner's standardisation activities' inquired about the previous involvement of partners in standardisation activities, and asked about their views on standardisation processes that GATEKEEPER project should be focused on, as well as key elements to be pushed for standardisation, and specific standardisation information in their own organisational context. The final part (Section C) titled 'Exploitable result description' further addressed partners' exploitable results.

As mentioned above, the results of the survey were integral for the design of the standardisation strategy.

3.3 Bilateral meetings with key standardisation players in the consortium

As at the time of the writing of D8.2 technological outputs to be considered for standardisation were not yet defined, in March 2021, MI and UDGA have initiated two bilateral meetings (11 March and 26 March 2021) with the project partners on standardisation and certification. In the context of standardisation, MI requested submissions of ideas for contributions, considering the outputs of D8.2. Potential topics were recorded in an excel titled WP8: Standardisation – Current and planned standardisation items.

WP8: STANDARDIZATION - Current and planned standardisation items

LEADING ORGANISATION	FOCAL POINT	SUPPORTING PARTNERS	SUPPORTING WP and Tasks	TOPIC	WHERE (SDO)
ERCIM	Dave Raggett, François Daoust		WP3, WP8, WP9	Progressing standardisation of Web of Things, Rules for mapping data between semantic vocabularies . RDF-star (easier link annotations, equivalent to property graphs), Cognitive AI (graphs and rules, combining symbolic and statistical approaches for human-like AI agents)	W3C
SALUD Aragon	Modesto Sierra			practical issues from service providers; compare how this match with the standards used by the technical teams	
HL7	Giorgio Cangioli, Catherine Chronaki		WP8.2, WP3, lead WP3.5	GK FHIR Implementation Guide; next steps conformance tested; ac	HL7
UDGA	Pasquale Annicchino				
MI	Sébastien Ziegler	MI, UDG	T8.2, T8.3	TBC	ITU
FUNKA	Susanna Laurin				
TUD	Julia Schellong			Standards for stand alone apps: IEC 82304-1:2016 norm and IEC Norm 82304-2:2016 regarding stand alone apps with close connection to IEC 62304 and IEC 80001-5-1	
UPM	Eugenio Gaeta	CERTH, W3C	WP3, WP4,WP5	Include JSON-LD contexts into OpenAPI in order to align content beween WoT and OpenAPI	

Figure 5 Current and planned standardisation items

Following up on the meetings, it became evident that consortium members have different understanding and involvement with standardisation. Therefore, bilateral meetings were set up during the summer of 2021 to further the partners' understanding. Based on the contributions to the excel sheet above, the following meetings were conducted:

- 7th June: ERCIM
- 9th June: MEDTRONIC
- 9th June: ECHALLIANCE
- 11th June: UPM
- 11th June: TUD
- 18th June: SALUD Aragon

Partners were requested to provide a minimum one-page long document with ideas for potential contributions. However, based on this new set, the following obstacles were identified:

- Lack of understanding on how standardisation works,
- Lack of understanding of the SDO landscape,
- Lack of understanding from WP8 towards the technicalities of the project,
- Lack of partners' awareness on what can be standardised.

As a result, MI started the development of a **Guidelines and Templates** document on an SDO basis. This is further detailed in Section 3.5 and Section 4. In parallel to this drafting

process, a **Standardisation contribution plan** (see Annex III) was set up to monitor the status of proposed contributions and to make sure that efforts are aligned with the KPIs set in D8.2 Standardisation strategy (see Table 1).

As a follow up to the actions undertaken, a meeting was hold on 26th November 2021 to share these latest updates with the active partners and to set up new actions on a partner and task leader basis. Partners, including HL7, FUNKA, and ERCIM were asked to finalise inputs to the guidelines and templates documents, to update the contributions plan, and to prepare draft contributions where relevant.

MI focused on getting in touch with partners who have not yet participated in the task, as well as contacting WP leaders to further share the work being done in T8.2. The following meetings have taken place:

- 14th December: MDT, UOW, UPM
- 16th December: WP4 general meeting
- 22nd December: WP7 general meeting
- 22nd December: MDT
- 22nd December: Medisanté
- 19th January: CERTH (WP3)
- 7th February: HL7
- 15th February: MYS

The outcomes of these discussions were used to further refine either the Guidelines and templates document, to extend the Standardisation contributions plan, or to work on specific contributions.

3.4 Development of templates for contributions to SDOs and fora

Based on the outcomes of the bilateral meetings, it was proposed that the development of SDO-specific guidelines and templates could further enhance not only the understanding of consortium members on how standardisation works but that it could facilitate the development of contributions. MI has shared with the consortium members active in standardisation (FUNKA, ERCIM, HL7, and CERTH) the draft ITU guidelines and templates in both Word and PowerPoint format requesting them to provide a similar guideline to their respective SDO(s). The final version of the guidelines includes the ITU, HL7, ETSI, CEN/CENELEC, Standards Norway, AIOTI and is attached to Annex I (Word version) and Annex II (PPT version). The development process of the guidelines and templates is further explained in Section 4.

3.5 Creation of contributions & submission

As mentioned above, a Standardisation contribution plan was set up to monitor the status of contributions (see Annex III). The document included the three Ws (WHAT, WHO, WHERE), as well as an additional WHEN and Status column. This document was then used as a guideline towards collecting information on submitted contributions, to set up bilateral meetings confirming the status of planned contributions, and to set up small working groups to further actions on joint contributions. Section 5 and 6 provides additional details on the contribution preparation and submission process.

3.6 GATEKEEPER Standardisation roadmap and timeline

The following figure summarises the timeline of events and key developments in the context of T8.2:

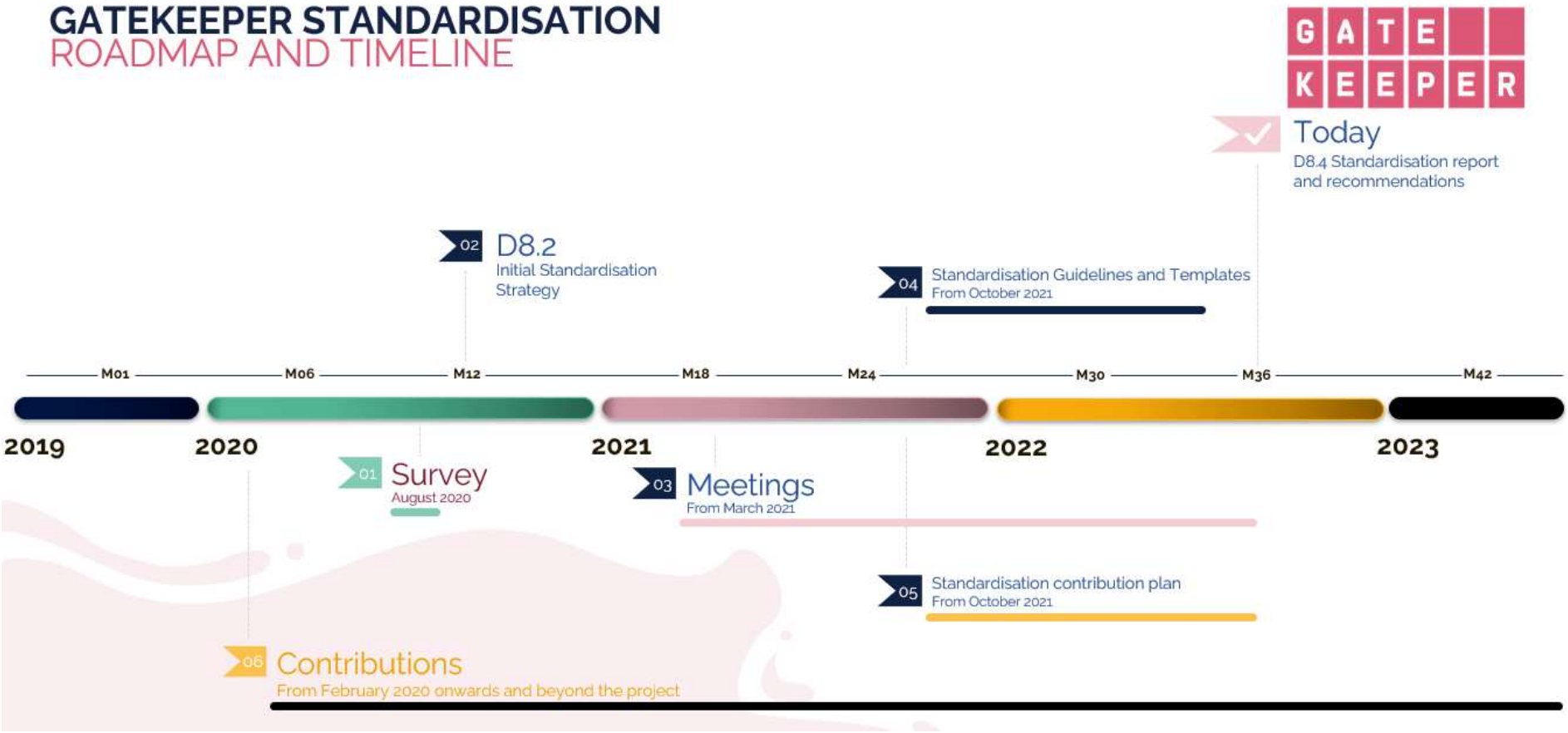

Figure 6 GATEKEEPER Standardisation roadmap and timeline

4 Development of guidelines and templates for SDOs

This section provides an overview of the different guidelines and templates that have been developed to facilitate contributions to the different standardisation organisation at global, regional, and international levels. The guidelines and templates document can be found in Annexes I and II of this deliverable.

4.1 Introduction

Based on bilateral meetings with the project consortium, out of the list of SDOs mentioned in D8.2, these are the most relevant with regards to the project activities. Due to this, the guidelines and templates document have been created for each organisation to facilitate the development of contributions. Its main objective was to provide a synthetic overview of the submission process at the specific SDOs and facilitate the contribution drafting procedure by the inclusion of templates.

4.2 Guidelines and Templates for SDOs at global level

4.2.1 ITU (International Telecommunication Union)

The International Telecommunications Union (ITU) functions as the UN agency for information and communication technology, and its' ITU Standardization (ITU-T) sector acts as an international standards development organisation. It publishes international standards called ITU-T Recommendations that define how telecommunications networks operate and interwork.

Mandat International serves as a Rapporteur on emerging technologies at the ITU-T Study Group 20 on IoT, Smart Cities and Communities. MI has set up the initial version of the Guidelines and Templates document in October 2021, including information on the standardisation work at the ITU-T, as well as an informative contribution template. This specific section in the document is structured into two main parts, the first one being a general overview of the ITU and ITU-T, the second being the actual step-by-step guideline on submitting contributions.

In the context of ITU-T, contributions can be considered in the topics of GATEKEEPER architecture, interoperability enablers, and data protection (as defined by D8.2). In general, draft contributions can be submitted by Member States, Sector Members, Associates, and academia participants in advance of Study Group meetings. The ITU-T has several requirements for contributions, as depicted on the figure below:

Figure 7 ITU-T contribution requirements

The following figure summarises the contribution submission process.

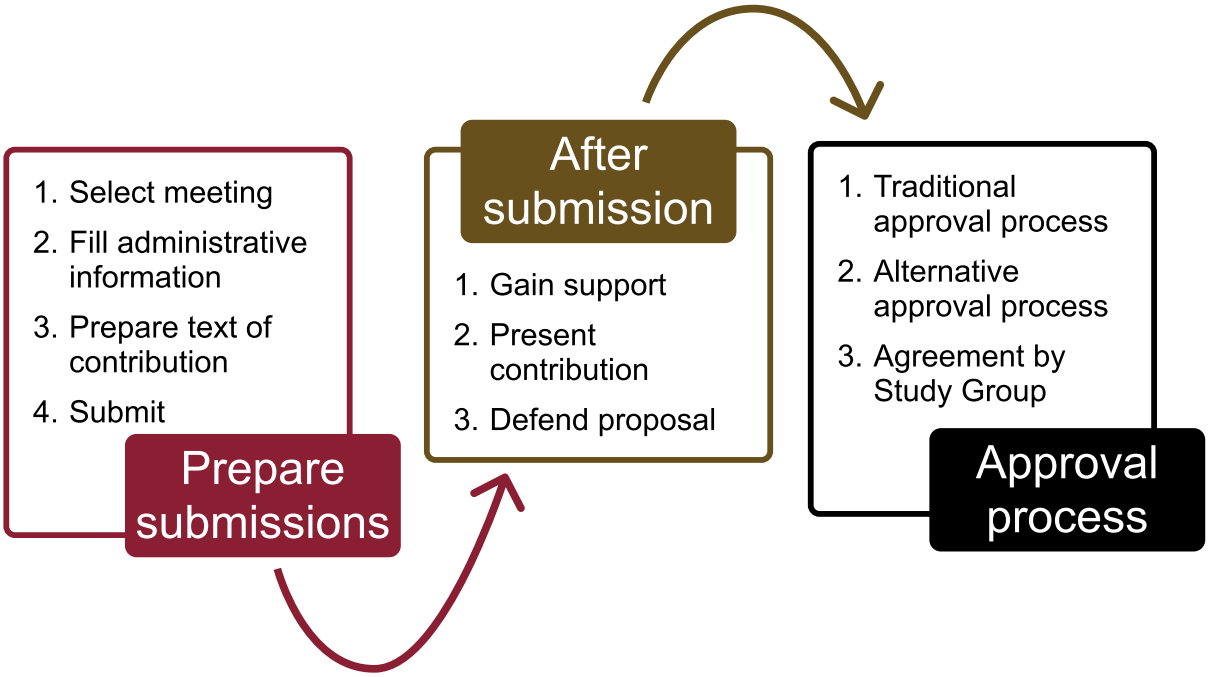

Figure 8 ITU-T contribution submission and approval process

In simple terms, a 4-step process must be followed to successfully submit contributions at the ITU-T, but the work is not done there yet. After the submission, contributions must be presented and defended, and they must go through a specific approval process, dependent on the type of the contribution.

MI integrated the downloadable empty template, as well as a draft contribution into this section of the Guidelines and Templates document. The draft is an informative contribution template of an event invitation (IoT Week). As further elaborated in Section 5.2, this contribution was not submitted in this format.

4.2.2 W3C (The World Wide Web Consortium)

The World Wide Web Consortium (W3C) is a de facto standards development organisation that develops standards (W3C Recommendations) in the context of the World Wide Web, including on topics, such as Web browsers, Web of Data, and Web of Things.

ERCIM took over the role of the European host from INRIA in 2003, and supports the interests of European members, as well as participating in numerous EU projects and PPP's such as AIOTI and DAIRO (formerly BVDA). ERCIM staff have played a key role in supporting work on the Semantic Web, Linked Data and the Web of Things, e.g., organising workshops on the Web of Things (2014), Graph Data (2019), and Imperfect Knowledge (2022), as well as leading efforts on developing Working Group charters, e.g., Web of Things (2016) and RDF-star (2022). ERCIM has included the first draft for W3C (and AIOTI) in December 2021, and further refined it in February 2022.

There are numerous ways to engage with W3C and push contributions forward, as shown in Figure 9.

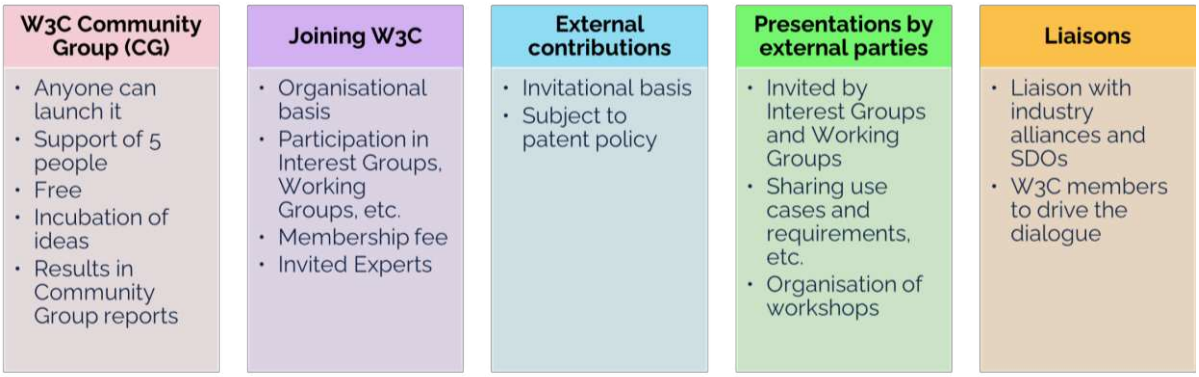

Figure 9 W3C contribution venues

In the context of GATEKEEPER, the Web of Things related developments can be moved forward at this SDO. Although multiple avenues exist, for GATEKEEPER, the best course of action is to target the W3C Web of Things Interest Group/Working Group and present the relevant GATEKEEPER developments. We would need to be able to explain the benefits of the changes we are proposing, and to show that we have considered alternatives and shown them to be less desirable.

4.2.3 HL7 (Health Level 7 International)

HL7 International is a not-for-profit standard developing organisation which develops and provides standards for the exchange, integration, sharing, and retrieval of electronic health information, supporting clinical practices and management. HL7 is a member of the GATEKEEPER consortium and integrated its specific guideline in December 2021.

HL7 standards vary from implementable specifications to Service or System Functional Models, from languages representing and sharing medical knowledge to Implementation independent Models. HL7 standards include base/primary standards (as HL7 FHIR or HL7 CDA) or derived products as functional profiles or Implementation guides.

The scope of the contributions can vary from proposing a specific change to a published standard up to propose a new standard. The following table summarises the tasks to be performed in the various activities.

Table 2 HL7 Activities and Scope

Scope Activity	Propose a new standard/new version	Contribute to a standard development	Comment a published standard
Informal community discussion	Suggested	Suggested	Suggested
Start a new project	Required	N/A	N/A
Join project/WG meetings	Part of the project life cycle	Required	Recommended
Commenting	Ballot comments are part of the project life cycle.	Optional	Required

HL7 welcomes and encourage newcomers to join in discussion and contribute to the development of its specifications. Membership is a requirement in order to take on an official leadership role, and it is also necessary to be able to participate in the formal voting process on proposed standards for free of charge. Non-members who are members of other specific SDOs may be entitled to reciprocal voting rights. Otherwise, non-members must always pay a fee.

Nevertheless, contribution to HL7 standards development is open to anyone. Non-members are free to join calls, participate in the HL7's community discussion forum, submit requests for change to HL7 specifications and vote on decisions in work group meetings. Interested parties can directly sign up on the HL7 website.

4.3 Guidelines and Templates for SDOs at regional level

4.3.1 CEN CENELEC (European Normalisation Committee / European Committee for Electro-technical standardisation)

The European (and national) standardisation process is typically rooted in an idea or a suggestion to a finished standard. This work is composed of different stages. In principle, an idea or proposal can come from anyone. In general, the proposer is expected to participate in the practical standardisation work, but it is not a requirement. The standardisation work is organised at national, European (CEN) and international (ISO) levels. At European level, CEN and CENELEC work in a decentralised way. The CEN and CENELEC's National Members work together to develop European Standards and other deliverables in many sectors to help build the European Internal Market of products and services, removing barriers to trade and strengthening Europe's position in the global economy. Standards should be based on consolidated results of science, technology, and experience, and aimed at the promotion of optimum community benefits. Standardisation projects are managed by technical committees, while standards are drawn up in working groups. FUNKA's Susanna Laurin is Chair of the CEN/CENELEC/ETSI Joint Technical Body eAccessibility, currently reviewing EN301549 – Accessibility requirements for ICT products and services under Mandate 587, as well as Committee Member of SAGA, the Strategic Advisory Group on Accessibility, and provided the CEN/CENELEC section in January 2022.

Also, a team member of the ECHAlliance is Committee Member of CEN/TC 428 - Digital Competences and ICT Professionalism, and part of the expert team contracted to deliver a CEN Technical Specification (CEN/TS) on "European Professional Ethics Framework for the ICT Profession (EU ICT Ethics)". Although this is not being developed within GATEKEEPER, its results will be considered within the project works and feed into the workflow of the project in what concerns ethical management.

Technically, anyone can propose work that will result in a European Standard. However, at CEN and CENELEC, the work is usually channelled by the members and follows the following process:

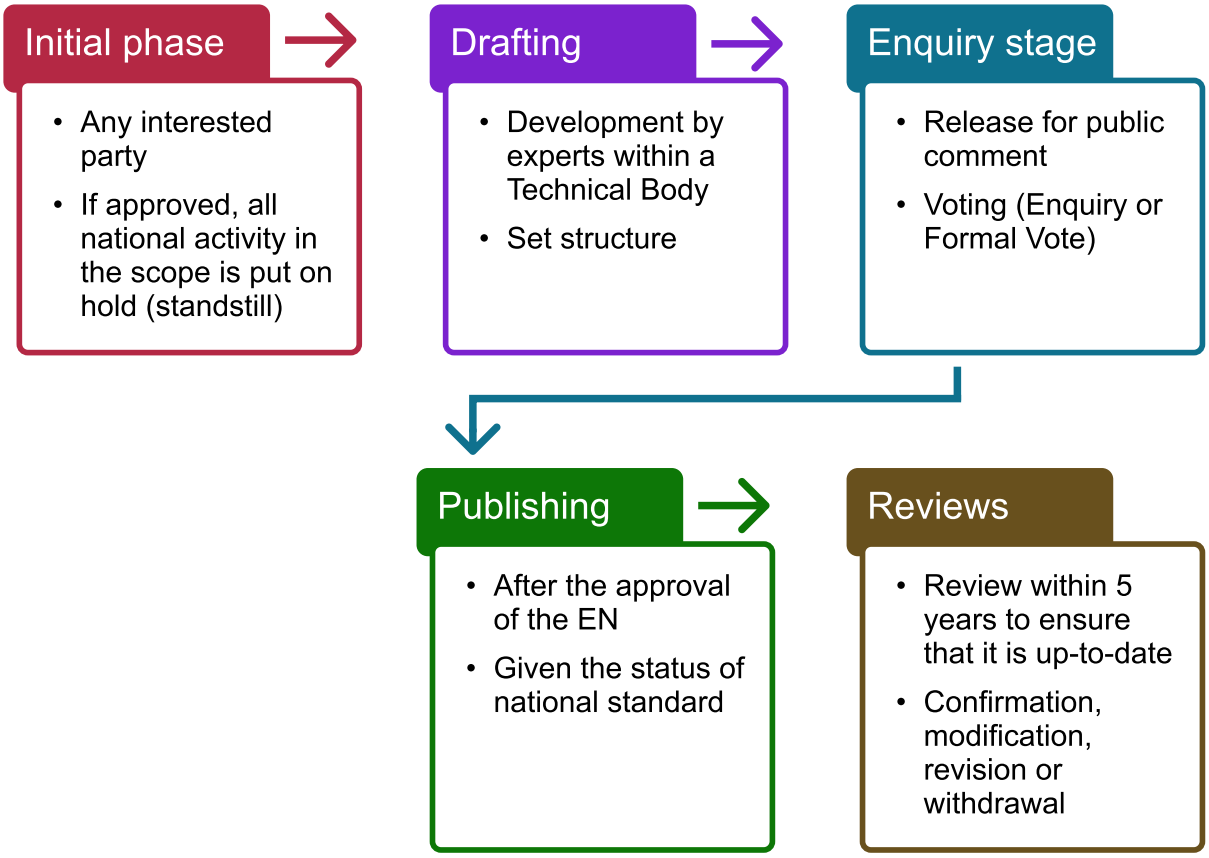

Figure 10 CEN/CENELEC standard development process

4.3.2 ETSI (European Telecommunications Standards Institute)

ETSI is one of the European regional SDOs that publishes over 2000 standards every year on topics such as cellular networks, smart cards, etc. ETSI standards are available free of charge. The types of standards and deliverables at ETSI include:

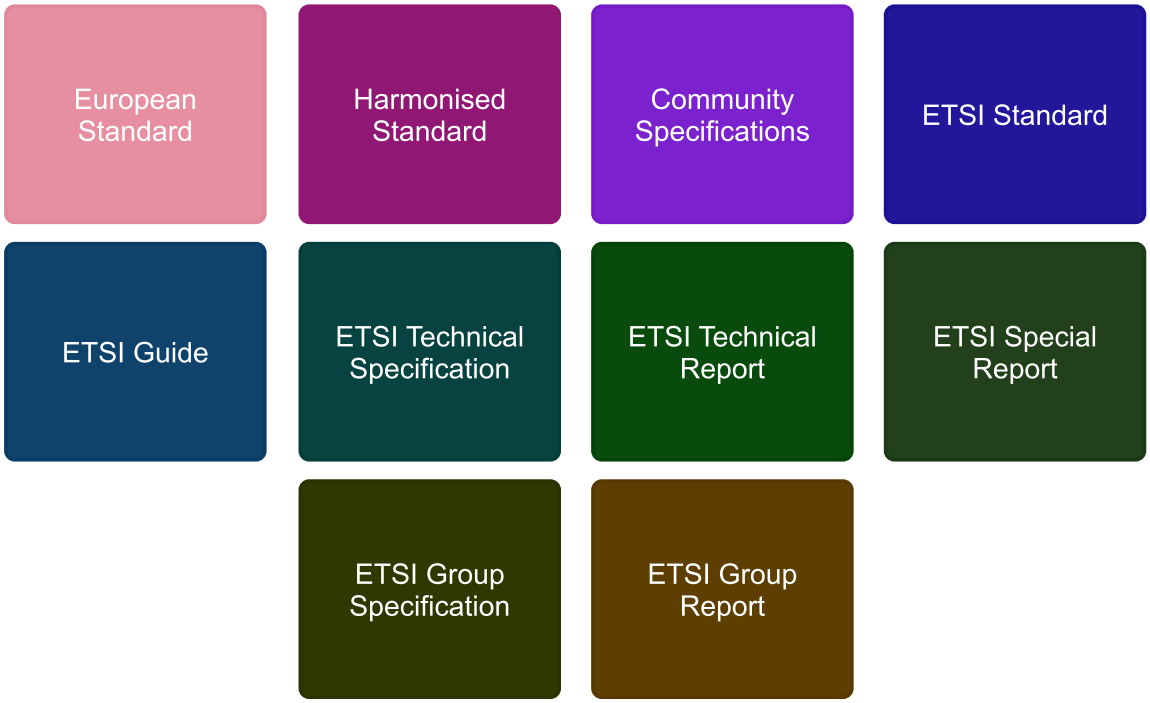

Figure 11 Types of ETSI Standards and Deliverables

FUNKA's Susanna Laurin is Chair of the CEN/CENELEC/ETSI Joint Technical Body eAccessibility, currently reviewing EN301549 – Accessibility requirements for ICT products and services under Mandate 587 while ERCIM has a strategic cooperation with ETSI. The ETSI section was included last in the document beginning of March 2022.

The ETSI standardisation process consists of two steps: (1) the creation of a standard and (2) the approval of a standard. This process is enhanced by a specific IPR Policy, as well as the principles of consensus and transparency.

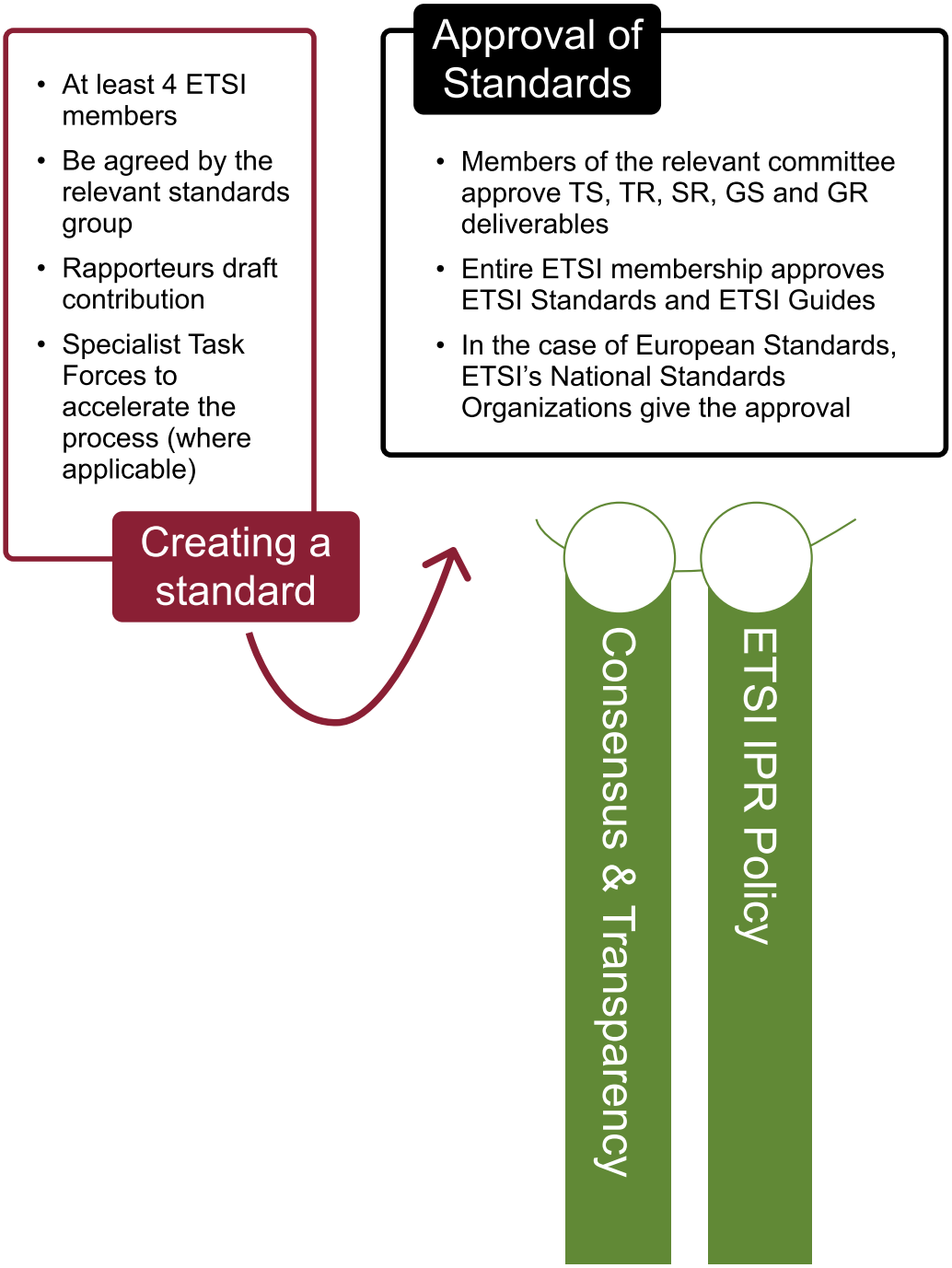

Figure 12 ETSI Standardisation process

The participation in some of ETSI technical groups is reserved to ETSI members whereas the participation to others is possible for both members and non-members upon signature of a specific agreement. In addition, a non-member organisation may be invited or authorised by the Chair of a Technical Body to attend meetings. The ETSI New and Emerging Technologies department reaches out to research organisations and develops the links between research projects and standardisation at ETSI.

ETSI has developed a full training cursus on standardisation for the use of organisations and academia to develop the skills and knowledge to successfully participate in

standardisation work. This material is made available freely for universities and trainers to use.

4.3.3 AIOTI (Alliance for Internet of Things Innovation)

AIOTI is a public-private cooperative activity among the industry, research institutions and the European Commission. It supports the coordination and exploitation across Horizon 2020 research projects on Internet of Things. ERCIM is an active member of AIOTI, their staff has contributed to the work on high-level architecture, edge computing, and semantic interoperability. The Guidelines and Templates document was complemented by information on the AIOTI process in December 2021.

One of the AIOTI working groups is specifically focused on standardisation and has 5 task forces, as depicted in the figure below:

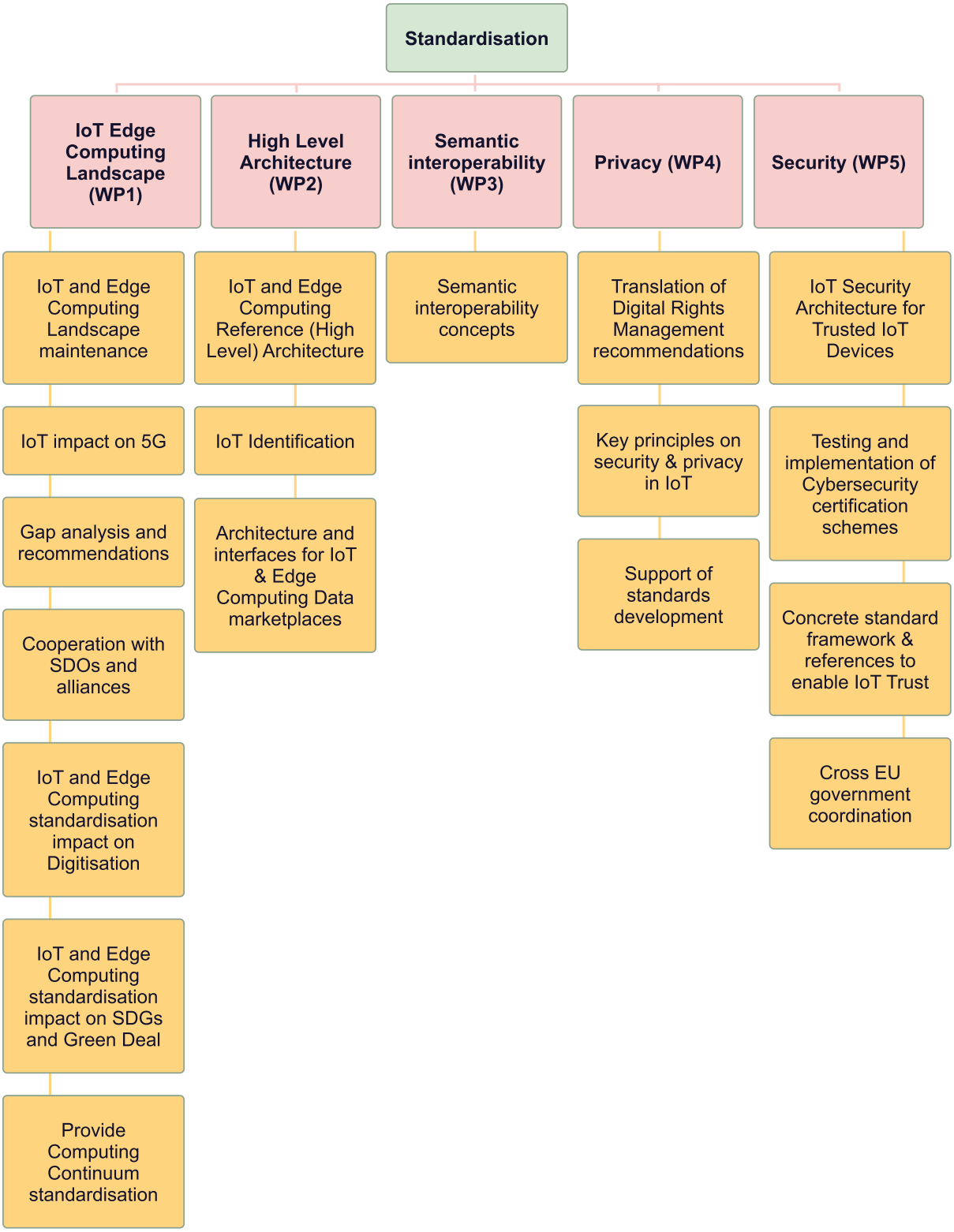

Figure 13 AIOTI Standardisation Working Group structure

Organisations can apply for membership. This includes an annual subscription fee.

4.4 Guidelines and Templates for SDOs at national level

4.4.1 Standards Norway

This section of the Guidelines and Templates document is intended to present national standardisation processes, from the perspective of Standards Norway. FUNKA was Committee Member of NS11030 – Equal access to services and NS11022 - Requirements for physical layout and interaction design for vending machines. This section was included in the document in January 2022.

Standards Norway is the Norwegian national standardisation body that is the member of CEN. It is committed to implement European standards as Norwegian Standards. It is also a member of ISO; selected ISO standards are integrated as Norwegian Standards as well. Additionally, SN is also the member of the Nordic cooperation on standardisation.

Proposals for a new standard can be put forward by members, the board of directors, sector boards, various stakeholder groups, other stakeholders and by Standards Norway. Standards Norway will assess the proposal based on societal and market needs in addition to access to resources. New project proposals from ISO and CEN are submitted to relevant stakeholders or standardisation committees for assessment of needs and interest.

SN prepares several types of documents, including:

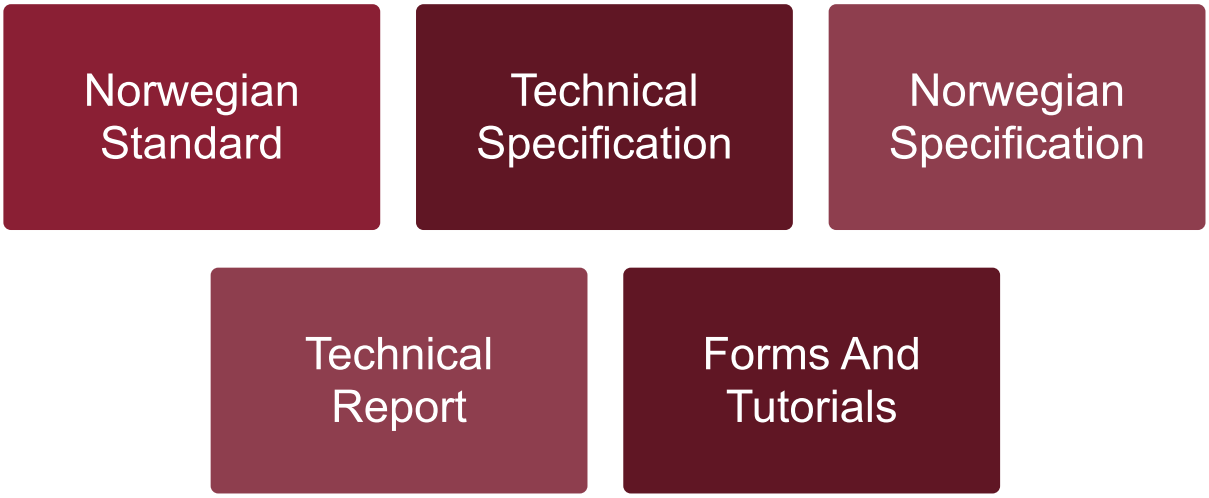

Figure 14 Standards Norway document types

The standard documents are developed based on the needs of society and the market and are formulated in accordance with the current writing rules and can include topics, such as:

- sustainability aspects (environment, climate, circular economy, etc.),
- universal design (UU) requirements,
- consumer aspects,
- adaptation for small and medium-sized businesses,
- gender aspects,

- suitability for conformity assessment.

The standardisation process consists of the following steps:

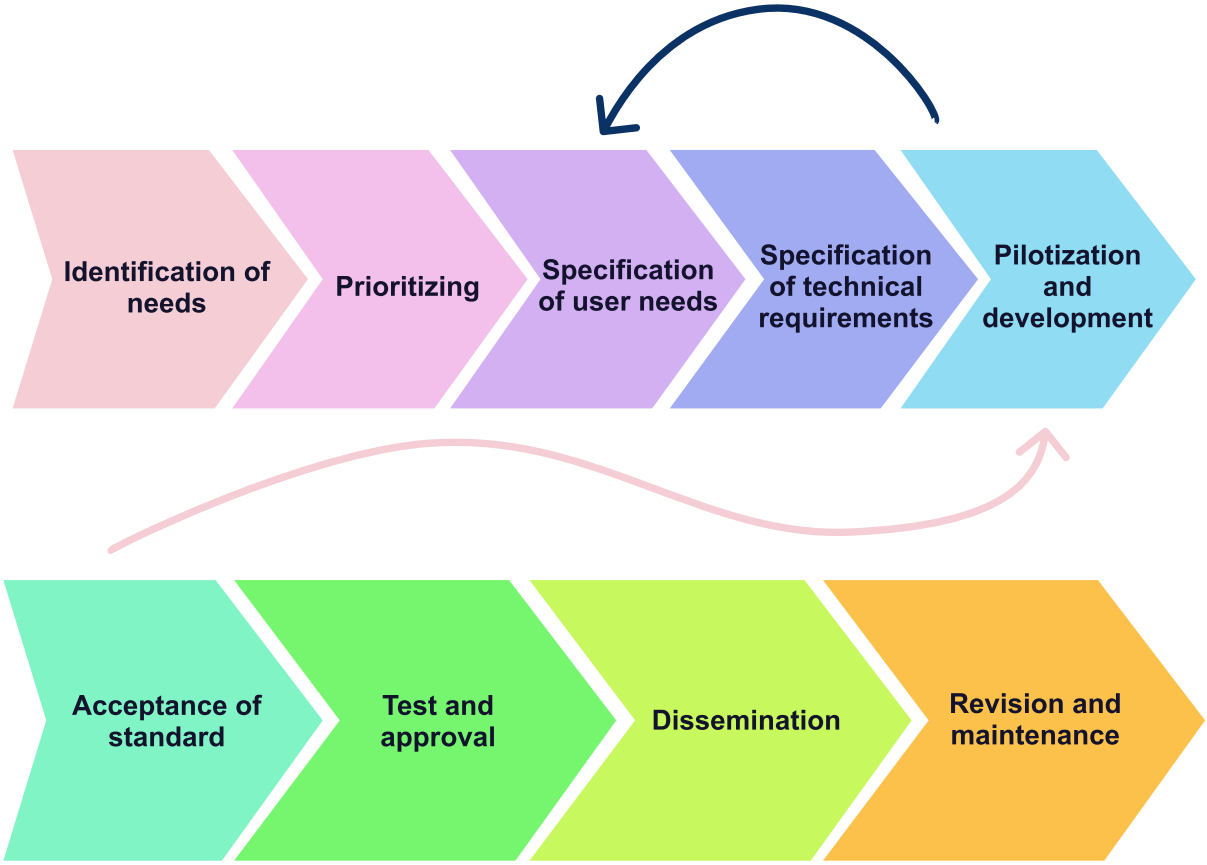

Figure 15 Standards Norway national process

5 Identification and development of elements to be considered for standardisation

This section provides an overview of the ideas that have been considered for standardisation, taking into account those mentioned in D8.2 and new ideas and that have been identified through bilateral meetings with the Gatekeeper partners.

5.1 Identified elements to be considered for standardisation in the strategy (D8.2)

The following synthetic strategy for standardisation was included in D8.2:

Table 3 Synthetic strategy for standardisation

WHAT	WHO			WHERE	
Research result to be standardized	**Related tasks**	**Lead expertise / Contributors**	**Lead SDO facilitator**	**SDO**	**Working Group**
GATEKEEPER architecture	T3.1, T3.2, T5.3	CERTH, ENG	FUNKA	CEN	CEN/TC 251: Health informatics
			ERCIM	AIOTI	WG 03: Standardization
			MI	ITU	SG20: Internet of things (IoT) and smart cities and communities (SC&C)
					ITU-T Focus Group on "Artificial Intelligence for Health" (FG-AI4H)
Interoperability enablers	T3.3, T3.4, T3.5, T4.1, T4.4, T4.5, T4.6, T5.3, T5.6, T5.7, T6.2	ERCIM, MYS, HL7, HPE, ENG, CERTH, MUL, OU, UPM	MI	ITU	SG20: Internet of things (IoT) and smart cities and communities (SC&C)
					SG16: Multimedia
				ISO	ISO/IEC JTC 1/SC 6: Telecommunications and information exchange between systems
			FUNKA	CEN	CEN/TC 293: Assistive products and accessibility
FHIR Implementation guides	T3.3, T3.4, T3.5, T4.2	HL7, ERCIM, MYS, UPM	HL7	HL7	FHIR Infrastructure Group

WHAT	WHO			WHERE	
Research result to be standardized	**Related tasks**	**Lead expertise / Contributors**	**Lead SDO facilitator**	**SDO**	**Working Group**
Web of Things	T3.3, T4.6, T4.2	ERCIM, UPM, CERTH	ERCIM, UPM, HL7 Europe	W3C	Web of Things Interest Group Web of Things Working Group
Data protection, security and GDPR compliance	T1.3, T1.4	UDGA	MI, UDGA	ECCP	Europrivacy international Board of Experts - Specification working group
			HL7	ISO	ISO/IEC JTC 1/SC 27: Information security, cybersecurity and privacy protection
			MI	ITU	SG17: Security
			ERCIM	ETSI	CYBER
			FUNKA	CEN	CEN/CLC/TC 8: Privacy management in products and services
					CLC/TC 62: Electrical equipment in medical practice
			HL7	HL7	FHIR Infrastructure Group

As mentioned before, the Standardisation strategy envisioned the submission of contributions based on five verticals and the active involvement of project partners in various SDOs. This preliminary list has since been consolidated to better reflect the technological outputs of GATEKEEPER. In the following sub-sections, we describe contribution ideas that were taken into consideration in the context of T8.2.

5.2 Additional elements to be considered for standardisation

Regarding HL7 and standardized international vocabularies, in the context of GATEKEEPER, a Gatekeeper HL7 FHIR implementation guide has been developed, feedbacks have been provided to the relevant HL7 WGs and the HL7 FHIR community. Moreover, the relevant SNOMED concepts have been added to the IPS sub-ontology to allow their worldwide free usage; new inclusion requests will be issued next year. Missing coded concepts, temporarily assigned by the GATEKEEPER project, will be requested to be added to the LOINC terminology.

6 Gatekeeper contributions to standardisation

This section provides an overview of the contributions that have been developed as part of the Gatekeeper approach to standardisation. A summary list of the contributions can be found in Annex III.

6.1 Europrivacy™/® Complementary Contextual Checks and Controls on eHealth

The approach towards personal data protection in Europe presents numerous challenges to the development and deployment of innovative technologies. The lack of compliance or incomplete compliance with personal data protection requirements (including on the EU and national levels) can impair the adoption, impact, and exploitation of the solutions and enablers developed in the context of GATEKEEPER.

A potential solution to this issue can be found in voluntary GDPR-specific certification schemes. They are developed in accordance with Art. 42 and 43 of the GDPR and demonstrate compliance with such rules and establish appropriate safeguards in the context of personal data protection.

Developed and extended through the Horizon 2020 European Research Programme (including projects, such as EAR-IT, Privacy Flag, Anastacia, Synchronicity) with financial support from the European Commission and Switzerland, the Europrivacy Certification Scheme can present a potential solution to the above-mentioned challenge. Europrivacy was co-created by several European research partners committed to promote personal data protection and in support to the implementation of the GDPR. Europrivacy is managed by the European Centre for Certification and Privacy (ECCP) in Luxembourg under the guidance of an international board of experts. ECCP has been granted the status of research centre by the authorities of Luxembourg and will keep continuous and close cooperation with the European research programme to maintain a high level of reliability of its certification scheme by leveraging on the European research community and a network of seasoned experts in data protection from all over Europe and beyond.

T8.3 enabled discussions with project partners and external stakeholders to provide a criteria extension for the Europrivacy Certification Scheme on eHealth. The developed criteria were pushed through various stages of validation at the Scheme Owner (ECCP) level, as well as through the Luxembourgish Data Protection Authority. After their validation and approval, the new criteria were incorporated into the Europrivacy Certification Scheme and brought to the European Data Protection Board (EDPB) which is currently considering the scheme for adoption. The EDPB has approved Europrivacy as the first European Data Protection Seal on 10th October 2022.[1]

The following sub-section provides a high-level overview of the developed complementary contextual criteria. Given the current evaluation status by the EDPB, the publication of the full text is not yet possible.

[1] https://edpb.europa.eu/our-work-tools/our-documents/opinion-board-art-64/opinion-282022-europrivacy-criteria-certification_en

6.1.1 Europrivacy eHealth criteria overview

Table 4 Europrivacy eHealth criteria overview

Identifier	High-level description
C5.3.1	If an IoT device processes special categories of data, including biometrics or health related data, a strong authentication methodology should be applied.
C.7.1.1	A DPIA should be performed if the ToE includes biometric, medical and health data.
C7.1.2	Use of pseudonymisation techniques if the ToE includes biometric, medical and health data.
C7.1.3	Multi-factor authentication should be used for human access verification.
C7.1.4	In case of contact tracing applications, restrictions apply (including manual activation, pseudonymous identifiers, and automatic change of identifier).

6.2 Chunk graphs & rules

Health data and metadata come in a variety of sources, protocols and formats, including information manually entered in forms. To simplify application development, it makes sense to introduce an abstraction layer that presents a common interface across these sources, decoupling applications from the complexity involved when dealing directly with the heterogeneity of the sources. Graph databases are an effective choice using vertices and connecting edges. Graphs can be operated on via low level graph APIs, graph query languages, and rule languages.

W3C's RDF for graphs is based on labelled directed edges, Vertices and labels are modelled as URIs for global identifiers, and so called "blank nodes" for local identifiers, scoped to a given graph. You can also use vertices for literals such as Booleans, numbers and strings. RDF further supports "Linked Data" via the means to dereference URIs to access collections of edges. That introduces challenges around security and access control. One relevant standard is W3C's Open Digital Rights Language (ODRL).

Recently RDF and Linked Data have been challenged by the emergence of a family of graph databases with rapid adoption by industry in comparison to RDF due to greater ease of use. Property graphs share with linked data the graph structure that makes them flexible and expressive. Property graphs, however, are not a standard technology since each system vendor has its own "flavour" of property graph. This causes interoperability problems and vendor lock-in, but it also hampers the emergence of a consolidated stack of tools for data querying, data validation, etc.

W3C is approaching this challenge with work on two approaches: the first is called RDF-star and is an extension to the Turtle serialisation format to support annotations on one or more edges. W3C is in the process of launching a new Working Group on RDF-star and associated extensions to the SPARQL query language. (SPARQL-star). For more details, see the proposed charter: https://w3c.github.io/rdf-star-wg-charter/.

The second approach offers a higher level representation using a simple, easy to author, syntax. This uses chunked sets of key-value pairs, where values are literals or references

to other chunks. Chunks builds upon decades of work in Cognitive Science. Chunks embrace both RDF and Property Graphs and are intended to address the common perception that RDF is hard to work with, something that has been holding back wider adoption of RDF across industry, including healthcare.

ERCIM's work in this area looks to the future of the GATEKEEPER platform, and to the promise of AI and automated reasoning over graph data. We want to make it simpler for developers to create innovative applications with health data. The contribution can be accessed on https://w3c.github.io/cogai/ and https://www.w3.org/community/cogai/.

More recently ERCIM has worked on plausible reasoning with imperfect knowledge, i.e., knowledge subject to uncertainties, incompleteness and inconsistencies, something that is impractical with traditional logic. This is inspired by the work of Alan Collins in the 1980's and seeks to mimic human reasoning in terms of developing and assessing arguments for and against a given premise, i.e., the kind of argumentation used for court cases, medical reasoning, safety and ethics. ERCIM has developed a web-based demonstrator, and co-organised a workshop during the Knowledge Graph Conference (KGC-2022), see: https://www.knowledgegraph.tech/kgc-2022-workshop-representing-and-reasoning-with-imperfect-knowledge/. Ongoing work by ERCIM staff aims to extend plausible reasoning to support causal reasoning, flexible quantifiers and comparisons. This combines symbolic knowledge (graphs) with sub-symbolic metadata. ERCIM is also working on cognitive architectures and combining System 1 and 2 reasoning, as a vision of a major step forward from today's Semantic Web, and key to next generation healthcare assistants.

6.3 Alignment of Gatekeeper Trust Authority with IDSA architecture

The Gatekeeper Trust Authority (GTA) developed in T4.5 keeps an audit trail of the actions done on Things (according to Web of Things standard) in blockchain. The said actions include the registration of a Thing in the Gatekeeper platform through the Marketplace or the Developer Portal, updates to its properties, its consumption/purchase by a Consumer, as well as its deletion from the platform. The usage of blockchain ensures immutability of the trail, traceability and non-repudiation. In the case of datasets in particular, exchange activities are logged in an implementation of the International Dataspaces Association (IDSA) Clearing House according to IDSA Reference Architecture 3.0[2].

The Clearing House logs all activities performed in the course of a data exchange through IDSA connectors. After a data exchange has been completed, both the Data Provider and the Data Consumer confirm the data transfer by logging the details of the transaction at the Clearing House, enabling billing of the transaction, and conflicts can be resolved (e.g., to clarify whether a data package has been received by the Data Consumer or not).

In the aim of performing this auditing process, but also to achieve the primary goals of data sovereignty and trust, IDSA connectors have been integrated with the Gatekeeper Marketplace. Data exchanges are possible only after the data provider and data consumer reach a bilateral agreement with selected usage policies and specified duration.

[2] https://internationaldataspaces.org//wp-content/uploads/IDS-Reference-Architecture-Model-3.0-2019.pdf

During the development, CERTH also performed beta testing on the IDS testbed[3], presented in "ICT Verticals and Horizontals for Blockchain Standardisation" and participated in "IDSA implementation" event. The event presentation is available in Annex IV.

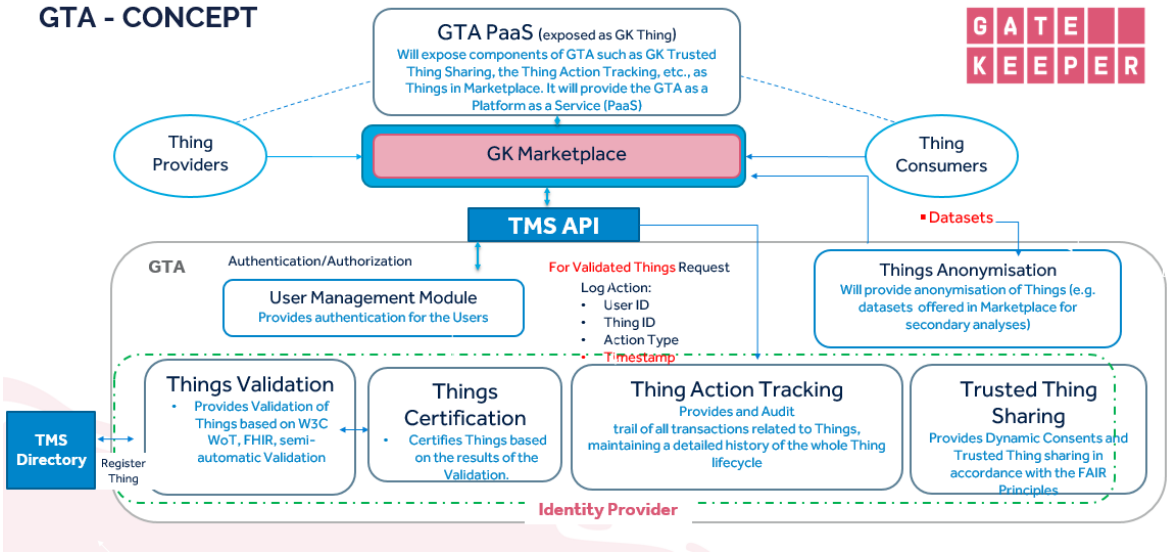

Figure 16 GTA conceptual architecture [D4.14]

[3] https://github.com/International-Data-Spaces-Association/IDS-testbed

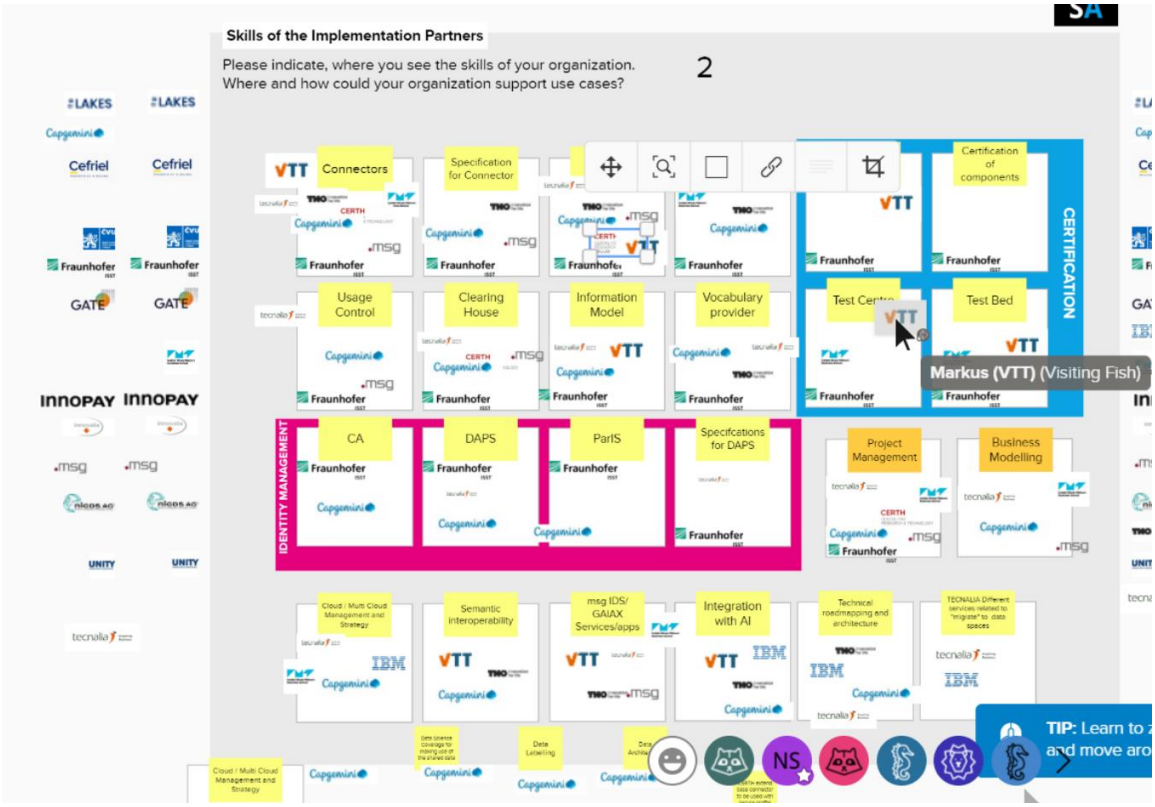

Figure 17 Screenshot from "Skills of the Implementation Partners", “IDSA implementation” online event March 2021

6.4 Overall project approach

A joint informative contribution was developed during the early months of 2022 with the support of CIBER, PredictBy, and Medisanté under the direction of Mandat International to share information on eHealth European research with Study Group 20 (IoT, smart cities and communities) Question 5 (Study of emerging digital technologies, terminology and definitions) of the International Telecommunications Union. During the first meeting of Study Period 2022-2024 on 18-28 July 2022 in Geneva, Switzerland, Mandat International shared the contribution with Members and informed SG20 about the current research efforts of the European Commission in the context of Horizon 2020 and Horizon Europe Research Programmes for the validation and trial of digital tools for early detection and intervention.

The contribution elaborated on the ambitions of GATEKEEPER and provided information on the use of the MAFEIP tool, as well as the digital cloud technology. The contribution advised SG20 to closely monitor the research developments of the eHealth domain and to address standardisation needs in coordination with the Focus Group.

The contribution was well received, and SG Members expressed their interest in getting further updates on the development of GATEKEEPER. The text of the contribution is included in Annex IV.

6.5 Intervention process modelling

6.5.1 Rationale and general description

This informative contribution is intended to present the need that has been detected within Gatekeeper and ODIN projects to standardise the description of the interventional (clinical) processes for one same type of Use Case in each Pilot Site where that Use Case has been deployed and is being studied. For example, COPD exacerbations management in Puglia and Aragon, within Gatekeeper project. This will facilitate the interpretation of data generated during the project, which will be integrated in data platforms equipped with AI, also developed during these projects.

Having a standardise description of the intervention process will facilitate new analysis of those data both for Gatekeeper project, focused on patients and for ODIN project, focused on Hospital Processes and new technologies. For example, it may allow AI-driven comparisons of Use Cases data among different Pilots in Gatekeeper or testing the robustness of new AI tools in ODIN.

This type of standardization will increase the level of data quality, a key requirement for data platforms fed with patient´s data where AI is being applied to identify new trends, models and relations within data in order to generate new information that will help in the early-detection, prevention, management and monitoring of prevalent diseases in Europe and also in the development and testing of new AI tools.

The initial work plan to be followed in order to achieve the process description was envisioned to start by choosing one single Use Case of study for each project (Gatekeeper and ODIN) and applying BPM (Business Process Management) methodology. The goal is to obtain a standard that represents the key process steps of that particular Use Case with enough information about the time-points of data generation and data descriptions.

6.5.2 Work Plan and next steps

Once the idea of this contribution was discussed with several partners of Gatekeeper project specialized on this topic, Medtronic was advised to contact BPM+ Health, a community of practice that works together in order to improve the quality and consistency of healthcare delivery by using several standards, such as BPMN, DMN and CMMN. Through collaboration, BPM+ Health applies these standards to clinical best practices, care pathways and workflows.

BPM+ Health is a working community managed by the SDO OMG (Objects Management Group), original developer of the BPMN (Business Process Model & Notation) Standard.

After holding a meeting with BPM+ Health, several matters were arisen for discussion with Gatekeeper and ODIN partners:

1. The idea and general description for this Contribution was perfectly aligned with the work done by BPM+ Health and a formal invitation was extended to start working with BPM+ health in order to present a formal contribution to the SDO OMG.
2. BPM+ Health works organized in working groups studying different topics related to BPM in Healthcare. The most relevant topics in this context, would be:
    a. Process Automation and Enablement
    b. Methodology
    c. Organizational Adoption and change management

d. Authoring

3. The way for a future collaboration to develop a contribution to the SDO OMG would be through working with one of these working groups. It would not be a "one-time" interaction, but rather through establishing a continuous relationship, attending the meetings of the working groups and having a mutually beneficial relationship.

6.5.3 Future impact and Conclusions

Given that Gatekeeper project was already very advanced and close to its finalization at the time that these discussions were held, the partners working on the standardization tasks of Gatekeeper and ODIN suggested performing this work with BPM+ Health in the context of ODIN project. The idea is to establish a formal interaction with BPM+ Health.

For this reason, the initial idea that was born in the context of Gatekeeper project, will be developed in ODIN project, providing a continuity to the standardisation work in the context of Horizon2020, improving the visibility and international impact of these activities through the collaboration with a Working Group specialized in BPM standards in healthcare.

Attendance to the working sessions of BPM+ Health is intended to give place to an informative contribution. This initial informative contribution is expected to be followed by a descriptive contribution related to ODIN project, where process standardization will have an impact in the way that Use Cases are being defined and deployed and may serve to increase the scalability and future exploitability of the project. If successful, ODIN process management standard could become a "gold standard" for the management of interventional processes for the European Hospitals of the Future.

6.6 Gatekeeper contribution to HL7 and SNOMED standards

In the context of Gatekeeper, there were an important contribution on HL7 and SNOMED standards. As previously mentioned, HL7 standards include base/primary standards (as HL7 FHIR or HL7 CDA) or derived products as functional profiles or Implementation Guides (IG). Gatekeeper contribution consisted of two parts: first, the deep analysis of all data that are necessary in a telemonitoring environment like the one defined within the GATEKEER project considering all the collectable data provided by device available in the Gatekeeper marketplace and then, the development of a HL7 FHIR derived product that is a Gatekeeper FHIR Implementation Guide[4]. The aim of this FHIR IG is to define all the profiles necessary for the purpose of the GATEKEEPER project that can be very useful also outside the project to support similar contexts. In details, after the deep analysis, there defined different Gatekeeper FHIR profiles for: appointment, different types of observations (blood glucose, blood pressure, body temperature, heart rate, oxygen saturation, sleep duration, number of steps, exercise tracking panel, acoustic measurements, activity level, number of floor climbed, living environment (humidity, temperature, pressure), NLP measurements, on, off and intermediate total hours measures, phonation vs silence measurement, social assessment (living status; tobacco

[4] https://build.fhir.org/ig/gatekeeper-project/gk-fhir-ig/index.html

use), verbal fluency, total hours of dyskinesia, word count, number of events measurement (e.g. med intakes; number of falls), pathology results, radiology results), different types of reports (laboratory results (also for self-tests), care plan, care team, condition, consent, encounter, family member history, location (the room where activity measures are taken), medication request (prescribed medicines), nutrition order, patient, practitioner, questionnaire response, research subject (the subject enrolment in the pilots), risk assessment (prediction of exacerbations for people with copd, heart failure or polymedicated people).

All these profiles were collected within a the new FHIR IG and feedbacks have been provided to the relevant HL7 WGs and the HL7 FHIR community.

In addition, during the development of the Gatekeeper FHIR profiles, some SNOMED concept were adopted. SNOMED Clinical Terms (CT) is a paid standard, but in the context of International Patient Summary (IPS), with a formalization of a license agreement between Snomed International and HL7 International, a sub-set of SNOMED codes where selected to create a list of terms that can be used worldwide free, the so called IPS Terminology[5].

Thanks to GATEKEEPER project, the IPS Terminology was extended with some new relevant SNOMED terms adopted in the Gatekeeper FHIR IG increasing the number of free usable standard codes.

6.7 Translator Web Of Things description to OpenAPI description with JSON-LD context

Within the project UPM has developed as open source software, publicly available in the UPM Gitlab server: https://gitlab.lst.tfo.upm.es/gatekeeper/cluster-demo/thing-descriptor-translator-web-service, a tool that translates the Web of Things - Thing Description into OpenAPI specifications.

This tool reads a Thing Descriptor specification and transforms it into an OpenAPI specification.

This process is achieved by iterating through the properties, actions and events of the Thing Description (called InteracionAffordances).

To construct all OpenAPI routes, we look in the InteracionAffordance of the Thing Description for the properties that specify the api method (get, put ,post) to construct the corresponding OpenAPI element.

To group the different InteractionAffordance under the same OpenAPI tag, we match the InteractionsAffordace url section by the same path, then we add the http and the OpenAPI path is fully defined.

As for the security schemes, Thing Description has as section dedicated to define the security schemes used in its properties.

We read this section and build each security scheme as the OpenAPI specification defines. Each Thing Description property can use different types of security schemes, and we do

[5] https://www.snomed.org/snomed-ct/Other-SNOMED-products/international-patient-summary-terminology

the same with this behaviour in OpenAPI. If any security type has a specific input variable (such as api_key auth type or bearer token) we do the corresponding transformations to match the types and variable names.

In terms of semantics, if any Thing Description property is tagged with the @type keyword we look up in the context the definition of the semantic type and build in the schema section of OpenAPI (when possible) the corresponding schema.

The main innovation behind the tools is to provide a wide spectrum interoperability between Web of Things standard and OpenAPI specifications. In the context of Web of Things the tools allows to reuse all the utility available for OpenAPI (like SwaggerUI) in order to improve developer productivity. This aspect is one of key functionality of the Gatekeeper developer dashboard where the SwaggerUI is used in order to provide an integrated environment for API testing. On the other hand the translator service is able to add semantic contexts to OpenAPI that nowadays are not supported, propagating the JSON-LD contexts of the Thing description into object schemas of OpenAPI maintaining the reference context of the ontology as extended OpenAPI field.

UPM is intended to share this project innovation as NPM package to the community behind Node JS at the end of the project.

6.8 How the GATEKEEPER FHIR Implementation Guide (GK FHIR IG) enable the certification of FHIR resources stored within the GK Data Federation Server

The GATEKEEPER FHIR Implementation Guide (GK FHIR IG) developed during the Project is a set of rules which constrain the very flexible structure of FHIR resources (e.g., most elements are optional, all data type components are optional) for a particular use case of the GATEKEEPER Project.

An important aspect of a FHIR IG for the certification issue is that the IG is also a FHIR resource. The Implementation Guide resource is a single FHIR resource that defines the logical content of the IG in both human and computable language. In details, it is formed, on one side, by a set of human readable web browsable pages, and on the other side, by a set of formal computable files that provide the computable processable definition of the structure of the FHIR resources. The human readable part is used by the developers to more easily understand the specification with a schematic view of the FHIR resources (profiles, value sets, code systems and concept map). The formal computable part can be used by application to automatically validate the FHIR resources. It means that the GATEKEEPER DATA FEDERATION Server by the use of the formal computable files the GK FHIR IG can automatically validate the FHIR resources generated by the client applications or by the GATEKEEPER DATA FEDERATION Integration Engine enabling their certification by the GATEKEEPER trust authority.

From the technical point of view, this is possible because the GATEKEEPER FHIR Implementation Guide was implemented with the FHIR Shorthand (FSH) language. FSH is a domain-specific language for defining FHIR artifacts involved in creation of FHIR IG and was created in response to the need in the FHIR community for scalable, fast, user-friendly tools for IG creation and maintenance. Conceived in September 2019 with the first version of the specification released in March 2020, FSH has been rapidly adopted by the FHIR community. Several significant tools for processing FSH have been developed, including SUSHI, a reference implementation and de facto standard compiler for transforming FSH into FHIR artifacts. FSH and SUSHI have been integrated with the HL7 FHIR

Implementation Guide Publishing tool, allowing seamless processing from FSH to a complete IG. FSH was approved as a Standard for Trial Use (STU 1) in May 2020 and a Mixed Normative - Trial Use Standard (R2) in February 2022. In the ensuing period, additional activity around FSH has driven improvements, new features, and maturation of FSH and related tools. The majority of language features of FSH are now normative, but certain newer language features are proposed as Trial Use[6].

The following figure represents the process of FHIR IG publication. HL7 EU, with a very close collaboration with the other GATEKEEPER partners to analyse the specific contest of use of the Project, developed the FSH files and prepared the content of web pages in human readable language (text and figure). Then HL7 EU configured and run SUSHI (steps 2 and 3), which, starting from the implemented FSH files, automatically generated the computer processable files that define the specifications (step 4). Finally, HL7 EU configured and run the HL7 FHIR IG publisher, which combined the computer processable files (produced in the step 4) with the human readable content to generate the complete IG (steps 5 and 6)[7]. The described process was performed several times during the Project, every time that the requirement chanced that there was the need to update the specification.

The GATEKEEPER FHIR Implementation Guide (GK FHIR IG) developed during the Project is available online[8].

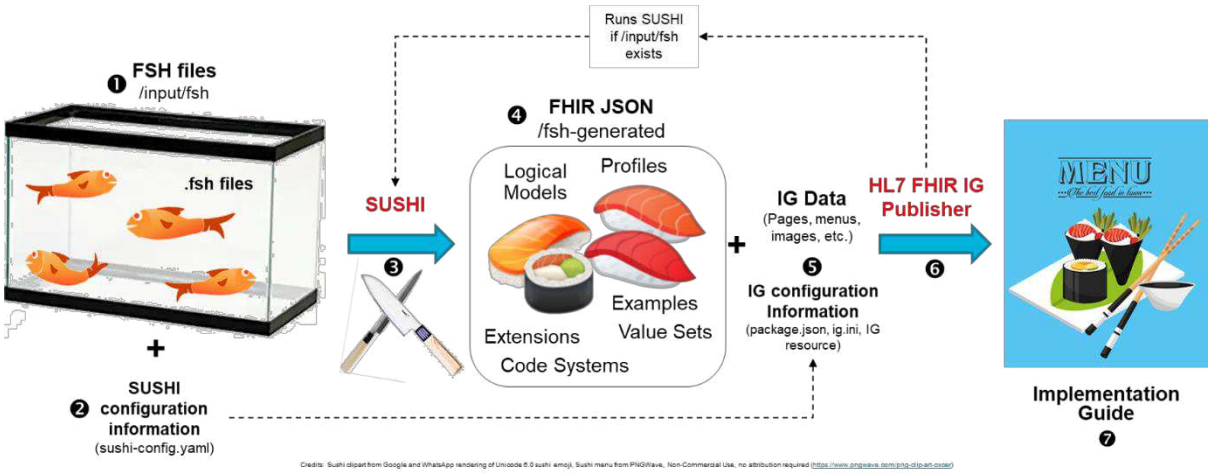

Figure 18 The process of publication of FHIR IG

The GK FHIR IG was presented to the HL7 International community in September 2022 in Baltimore, during the 36th Annual Plenary, Working Group Meeting (WGM) and FHIR Connectathon[9]. In particular HL7 EU reported the activities performed in the GATEKEEPER Project and described the structure of the specification of the GK FHIR IG to the HL7

[6] https://build.fhir.org/ig/HL7/fhir-shorthand/

[7] https://build.fhir.org/ig/HL7/fhir-shorthand/overview.html

[8] https://build.fhir.org/ig/gatekeeper-project/gk-fhir-ig/.

[9] https://www.hl7.org/events/working_group_meeting/2022/09/

Mobile Health Working Group (WG)[10]. The WG well received it especially the profiles related to the physical activity monitoring. At the U.S. level, the Physical Activity Alliance (PAA) sponsored a 2022 initiative to create an HL7 FHIR IG[11] whose physical activity monitoring profiles are well aligned to those of the GK FHIR IG.

[10] https://confluence.hl7.org/display/MH/2022+September+WGM+-+Mobile+Health+WG

[11] https://build.fhir.org/ig/HL7/physical-activity/

7 Monitoring

This section provides an overview of the key performance indicators that were established for this task and looks at the progress made by the WP8 team. It also provides a high-level view of the monitoring activities carried out by MI to track the progress of contributions.

7.1 Target outcomes and KPIs

In order to better monitor the progress of T8.2, the following KPIs have been defined for standardization according to the priority of the consortium members:

Table 5: KPIs

KPI	Target	Value M48
Number of contributions to SDOs	10	10
Percentage of joint contributions	50%	30%
Percentage of identified innovations brought to standardization succeeding to be taken into account in draft standards	50%	50%

It is worth specifying that the 'contributions to SDOs' not only allude to new draft recommendations and contributions to existing standards but also include other forms of collaborations with SDOs including presentations, demos, tutorials, and participations in target events. The numbers above reflect the consideration of various types of contributions made by partners ranging from presentations (at target events), submission of descriptive/informative documents to full-fledged recommendations/standards. This way, we have managed to achieve the initial KPI for 10 contributions submitted, as showcased in the previous section and Annex III.

Unfortunately, the Target for the number of joint contributions was not yet achieved by the time of writing of the present deliverable. In some cases, it is difficult to measure to what extent individual contributions by partners were supported by others at any point of the development. Regarding the percentage of contributions taken into account for standards, half of the contributions were already submitted as recommendations and can be considered full-fledged standards, including:

1. Europrivacy Complementary Contextual Checks and Controls on eHealth (ECCP)
2. Chunk graphs & rules (W3C)
3. HL7 and SNOMED standards contribution (HL7)
4. Data Space Radar (IDSA)
5. FHIR Implementation Guide (GK FHIR IG) for the certification of FHIR resources (HL7)

For the remaining contributions, it is not possible, at this time to determine whether they will directly lead to the generation of new standards, as standardization activities take a considerable amount of time to be materialized. For example, the contribution presented to ITU led to significant interest on the project and we have been invited to provide an updated version presenting the main project results in the upcoming Study Group 20 (to take place in Geneva from 1-12 July 2024) to several of the SG Questions for their

consideration. However, this would take place once the project has officially finalized, and thus further reporting is not feasible.

As mentioned before, at the onset of the preparation for submitting contributions to selected SDOs, several meetings were held both in a group format and partner-by-partner basis. Later, and particularly during the last year of the project communications shifted to email follow-ups and personal discussions during in person meetings.

8 Recommendations for future standardisation efforts

With regards to the key outputs and learning outcomes of the standardization activities undertaken for Gatekeeper, we would like to acknowledge the significant achievements made thus far, as they have the potential for replicability in other research projects. Notably:

1) The Key Performance Indicators (KPIs) set for standardization have been successfully met, demonstrating the effectiveness of our approach. To build upon this success, it is recommended to intensify the alignment among technical partners. Enhanced coordination between the development teams and the organizations leading standardization efforts, especially in the initial mapping of standards, is likely to foster a greater number of joint contributions to standardization. This approach will leverage the collective expertise and insights of various stakeholders.

2) The positive feedback from several partners and external organizations underscores the substantial value of the activities conducted under this task. The unification of standardization guidelines and templates, as detailed in Annexes I and II of this deliverable, has been particularly beneficial. These resources have provided clear guidance, helping partners and external bodies to navigate and better understand the contribution process more effectively. This not only streamlines the standardization process but also ensures a more cohesive and comprehensive approach to achieving our overarching goals.

3) The project notably contributed to the development, agreement, and introduction of specific e-health criteria within the Europrivacy certification scheme. This scheme is particularly noteworthy as it is currently the only European Data Protection Board (EDPB)-approved European data protection seal. The integration of these e-health criteria into Europrivacy aligns seamlessly with the GATEKEEPER project's goals, enhancing the quality of life of citizens and demonstrating efficiency gains in health and care delivery across Europe. This achievement underlines the project's commitment to advancing healthcare standards and data protection in the European digital health sector. This successful integration of e-health criteria into the Europrivacy certification scheme, as achieved by the GATEKEEPER project, serves as a model of excellence and should be considered a best practice for other EU-funded research projects. By replicating this approach, these projects can not only contribute to advancing sector-specific standards but also align their outcomes with broader EU data protection and privacy regulations. This replication will ensure a consistent and high-quality approach to data handling and privacy across various research and development initiatives, ultimately strengthening the EU's position in global digital health innovation.

Annex I: Standardisation Guidelines and Templates

Annex I is provided as a separate document.

Annex II: Standardisation Guidelines and Templates (PPT)

D8.4 ANNEX
GATEKEEPER
STANDARDIZATION
GUIDELINES AND TEMPLATES

RENÁTA RADÓCZ
ADRIAN QUESADA RODRIGUEZ
MANDAT INTERNATIONAL

T8.2 STANDARDIZATION
STANDARDIZATION GUIDELINES AND TEMPLATE

Objective

- Introduce standards development processes
- Provide guidance on the contribution submission process
- Provide a repository of templates and guidelines

Content

- About SDOs: ITU, W3C, HL7, ISO, IEC, TBC
- How it works
- How to submit contributions
- Next steps

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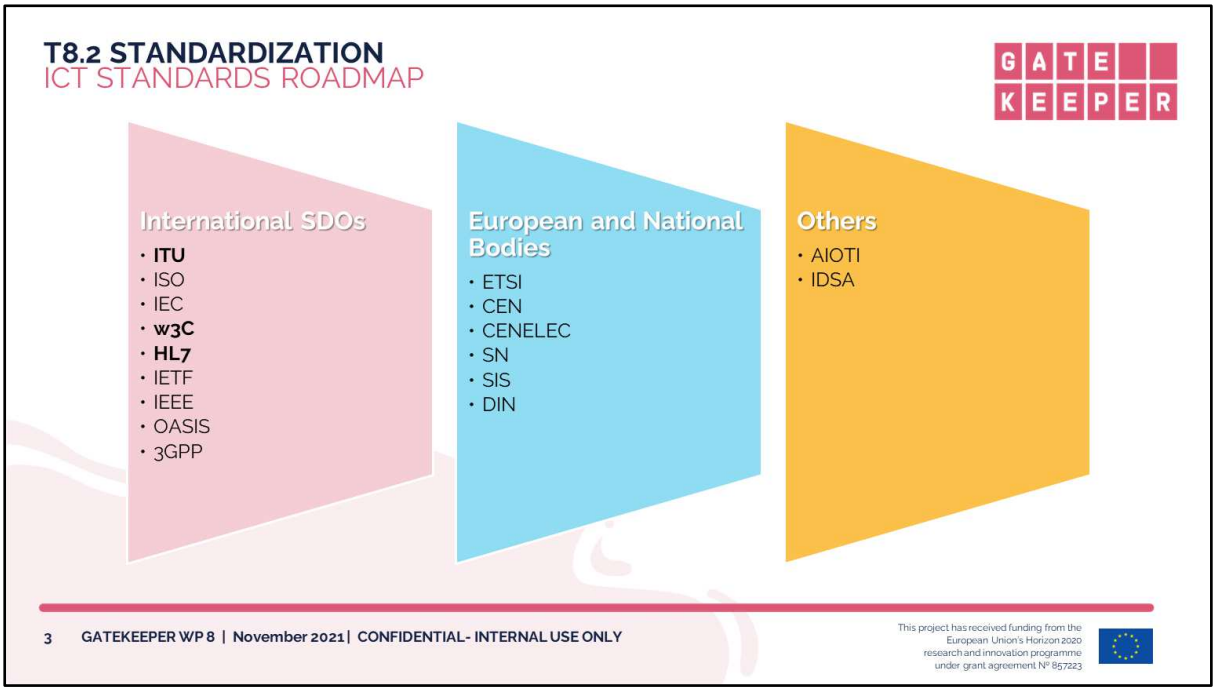
T8.2 STANDARDIZATION
ICT STANDARDS ROADMAP
International SDOs
• ITU
• ISO
• IEC
• w3C
• HL7
• IETF
• IEEE
• OASIS
• 3GPP
European and National Bodies
• ETSI
• CEN
• CENELEC
• SN
• SIS
• DIN
Others
• AIOTI
• IDSA
3 GATEKEEPER WP 8 | November 2021 | CONFIDENTIAL- INTERNAL USE ONLY
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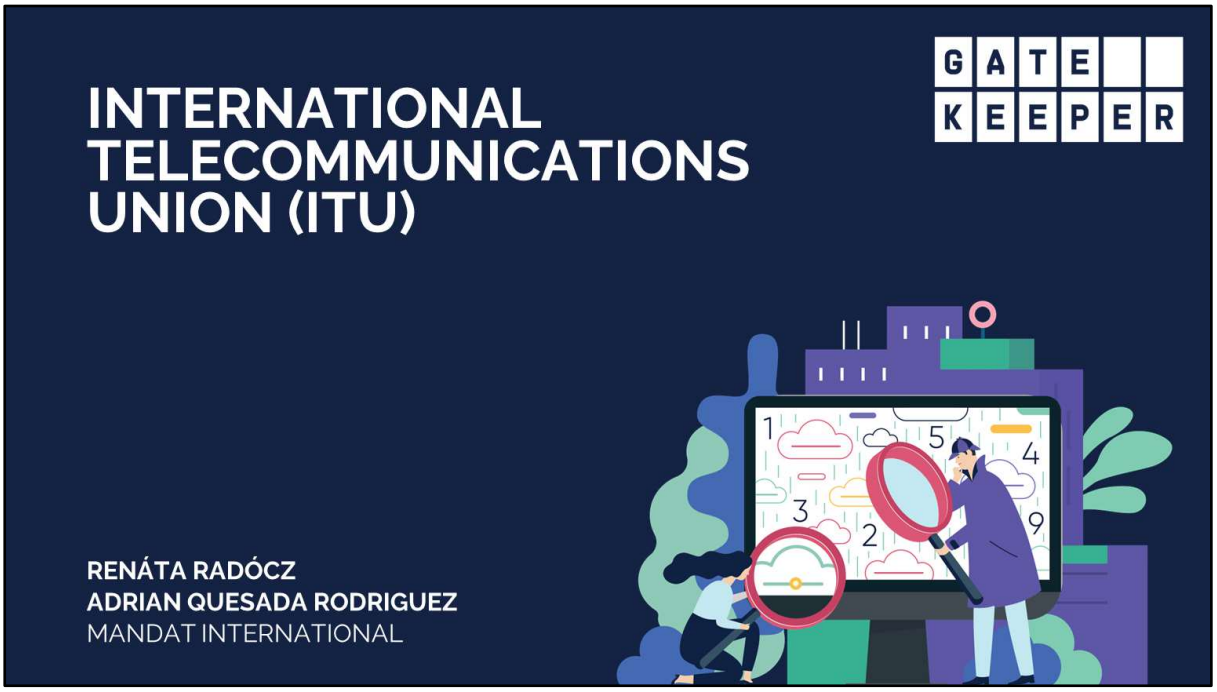
INTERNATIONAL TELECOMMUNICATIONS UNION (ITU)
RENÁTA RADÓCZ
ADRIAN QUESADA RODRIGUEZ
MANDAT INTERNATIONAL

INTERNATIONAL TELECOMMUNICATIONS UNION
ABOUT

- UN Agency for ICT
- 193 member states
- 700+ private sector
- 150+ academia

3 sectors:

1. **ITU Radiocommunication (ITU-R)** → coordinating radio-frequency spectrum and assigning orbital slots for satellites
2. **ITU Standardization (ITU-T) → Establishing global standards**
   - Platform for governments and private sector too coordinate the development of international standards
3. **ITU Development (ITU-D)** → bridging digital divide

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INTERNATIONAL TELECOMMUNICATIONS UNION
HOW IT WORKS

Contributions

- Submitted by Member States, Sector Members, Associates, and academia participants in advance of SG meetings
- Intended to move the work forward by addressing specific Questions

Concisely drafted	International terminology	Official language
Contributions must be concisely drafted and clearly written. Must be comprehensive and universally understandable.	Contributions must use international terminology and units.	Contributions must be in one or more of the official ITU-T languages.

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INTERNATIONAL TELECOMMUNICATIONS UNION
HOW TO CONTRIBUTE

- For faster processing and publishing, a template has been prepared for delegates who wish to make a contribution to the ITU-T, in order to minimize formatting at the receiving end.
- ITU-T provides several resources on how to prepare contributions.
- *4-step process to submit contributions:*
    1. Select meeting
    2. Fill administrative information
        - Indicate source
        - Include title
        - Indicate purpose (action/information)
        - Enter contact details
        - Include keywords and prepare abstract
    3. Prepare text of contribution
    4. Submit

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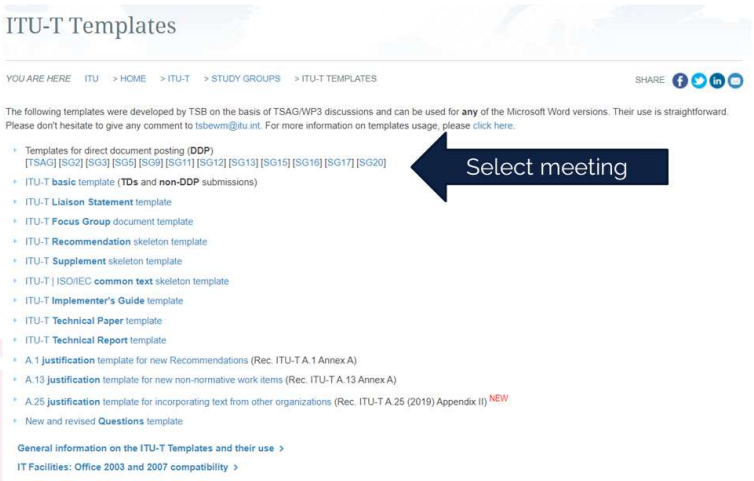
INTERNATIONAL TELECOMMUNICATIONS UNION
SELECT MEETING



1. Go to the ITU-T templates webpage https://www.itu.int/en/ITU-T/studygroups/Pages/templates.aspx
2. Select the Study Group of your interest (SG20)
3. Click and download the template

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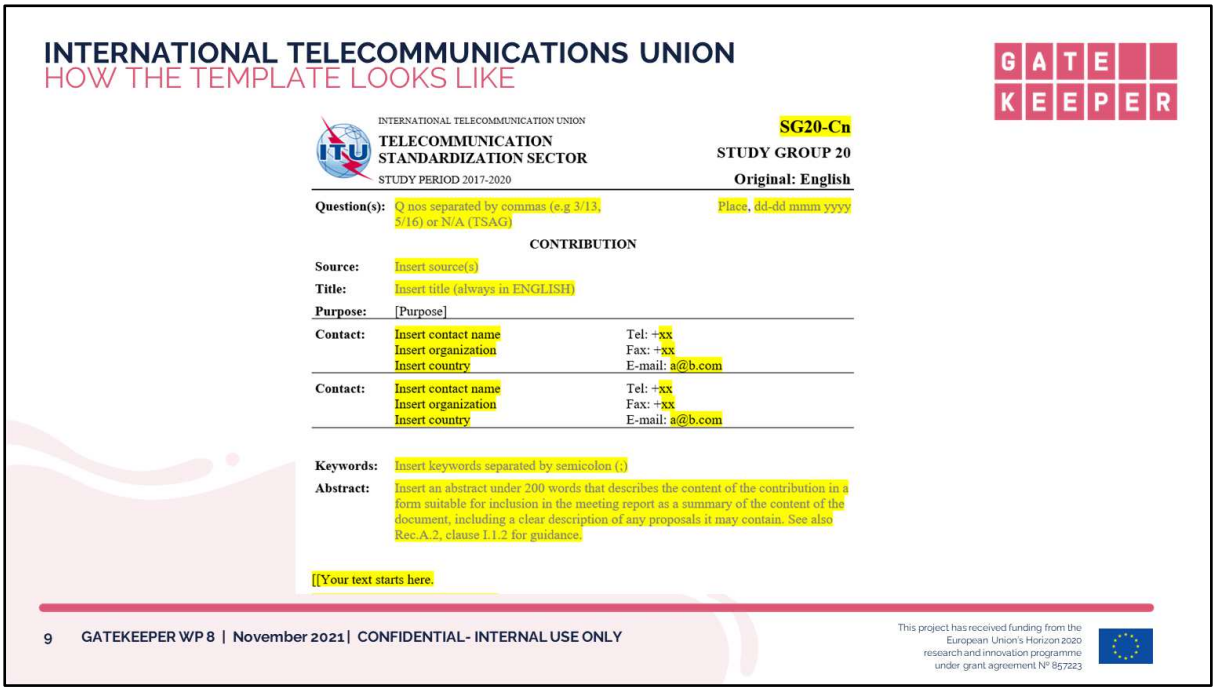
INTERNATIONAL TELECOMMUNICATIONS UNION
HOW THE TEMPLATE LOOKS LIKE



INTERNATIONAL TELECOMMUNICATION UNION
TELECOMMUNICATION STANDARDIZATION SECTOR
STUDY PERIOD 2017-2020

SG20-Cn
STUDY GROUP 20
Original: English

Question(s): Q nos separated by commas (e.g 3/13, 5/16) or N/A (TSAG) — Place, dd-dd mmm yyyy

CONTRIBUTION

Source:	Insert source(s)	
Title:	Insert title (always in ENGLISH)	
Purpose:	[Purpose]	
Contact:	Insert contact name Insert organization Insert country	Tel: +xx Fax: +xx E-mail: a@b.com
Contact:	Insert contact name Insert organization Insert country	Tel: +xx Fax: +xx E-mail: a@b.com

Keywords: Insert keywords separated by semicolon (;)

Abstract: Insert an abstract under 200 words that describes the content of the contribution in a form suitable for inclusion in the meeting report as a summary of the content of the document, including a clear description of any proposals it may contain. See also Rec.A.2, clause I.1.2 for guidance.

[[Your text starts here.

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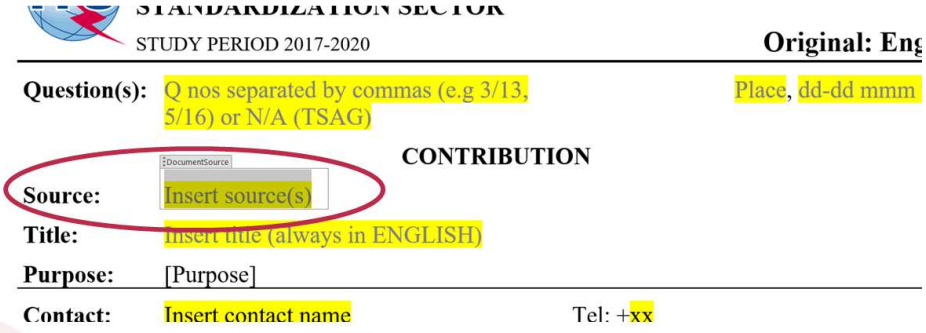
INTERNATIONAL TELECOMMUNICATIONS UNION
INDICATE SOURCE



STANDARDIZATION SECTOR
STUDY PERIOD 2017-2020 — **Original: Eng**

Question(s): Q nos separated by commas (e.g 3/13, 5/16) or N/A (TSAG) — Place, dd-dd mmm

CONTRIBUTION

Source:	DocumentSource Insert source(s)
Title:	Insert title (always in ENGLISH)
Purpose:	[Purpose]
Contact:	Insert contact name — Tel: +xx

At the Source, you need to indicate the entity which you will represent at the meeting.

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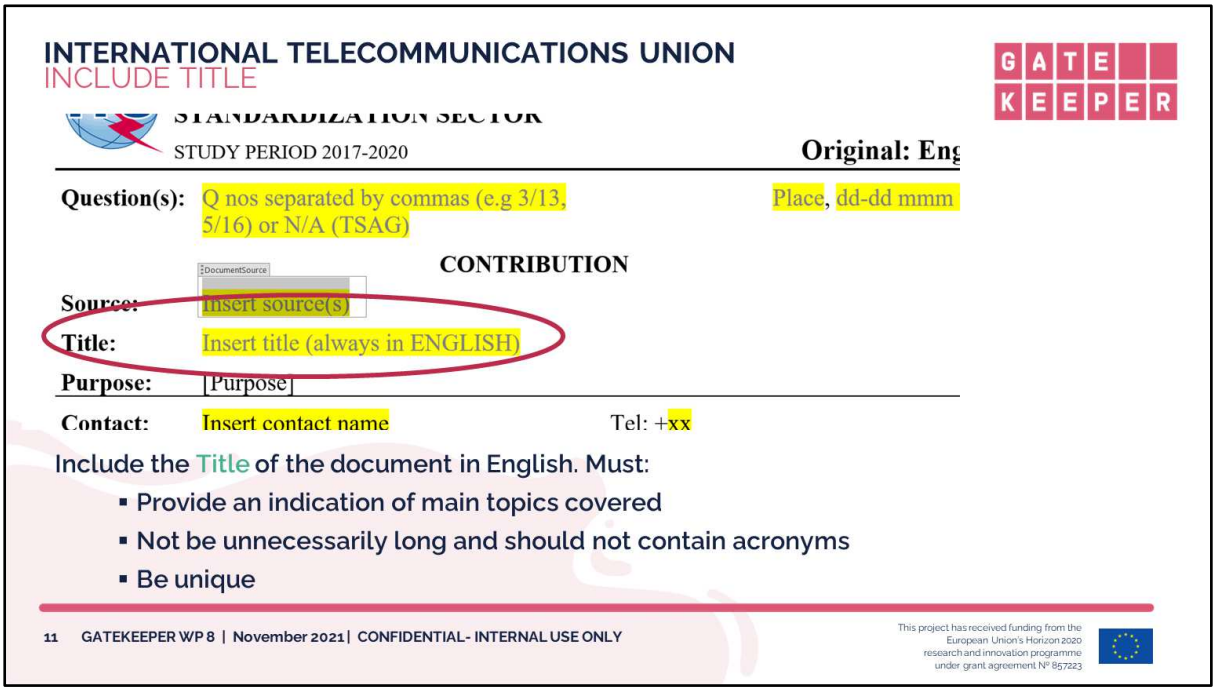

INTERNATIONAL TELECOMMUNICATIONS UNION
INCLUDE TITLE

STANDARDIZATION SECTOR
STUDY PERIOD 2017-2020 **Original: Eng**

Question(s): Q nos separated by commas (e.g 3/13, 5/16) or N/A (TSAG) Place, dd-dd mmm

CONTRIBUTION

Source: Insert source(s)
Title: Insert title (always in ENGLISH)
Purpose: [Purpose]
Contact: Insert contact name Tel: +xx

Include the Title of the document in English. Must:

- Provide an indication of main topics covered
- Not be unnecessarily long and should not contain acronyms
- Be unique

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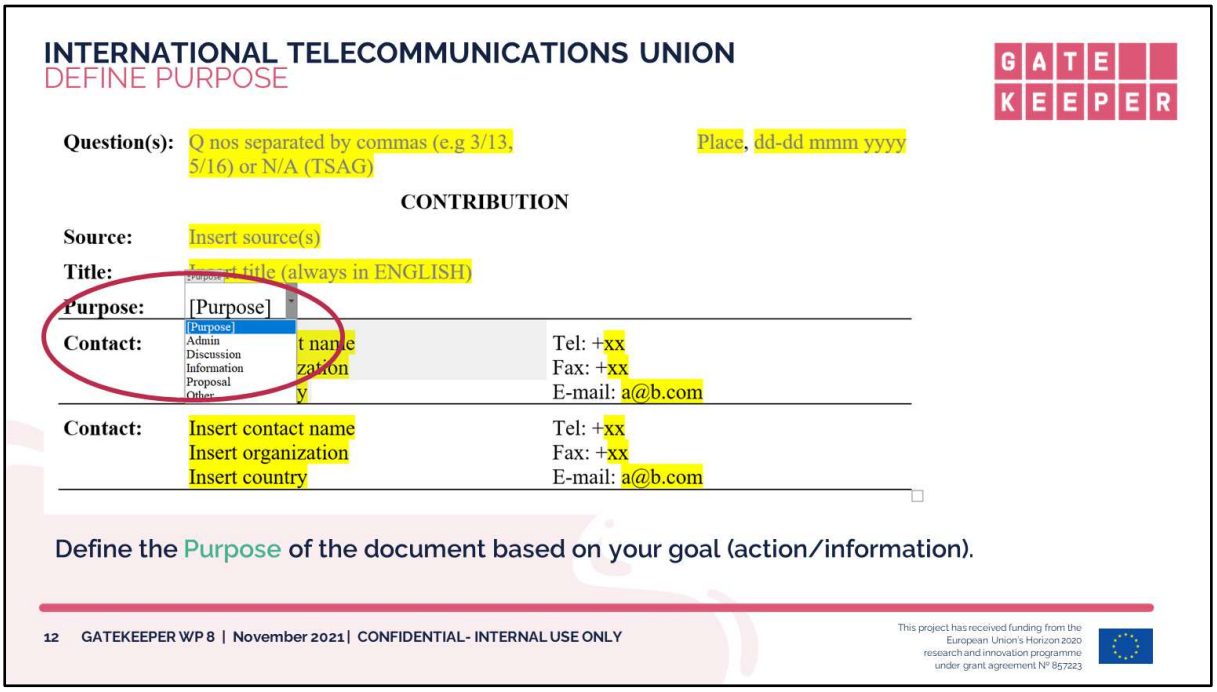

INTERNATIONAL TELECOMMUNICATIONS UNION
DEFINE PURPOSE

Question(s): Q nos separated by commas (e.g 3/13, 5/16) or N/A (TSAG) Place, dd-dd mmm yyyy

CONTRIBUTION

Source: Insert source(s)
Title: Insert title (always in ENGLISH)
Purpose: [Purpose] (Purpose, Admin, Discussion, Information, Proposal, Other)
Contact: t name / zation / y — Tel: +xx, Fax: +xx, E-mail: a@b.com
Contact: Insert contact name, Insert organization, Insert country — Tel: +xx, Fax: +xx, E-mail: a@b.com

Define the Purpose of the document based on your goal (action/information).

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INTERNATIONAL TELECOMMUNICATIONS UNION
DEFINE PURPOSE

Purpose:	[Purpose]	
Contact:	Insert contact name Insert organization Insert country	Tel: +xx Fax: +xx E-mail: a@b.com
Contact:	Insert contact name Insert organization Insert country	Tel: +xx Fax: +xx E-mail: a@b.com

Enter your contact details for the contribution. These details will be displayed in the footer of the final document.

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INTERNATIONAL TELECOMMUNICATIONS UNION
INCLUDE KEYWORDS AND PREPARE ABSTRACT

Keywords: Insert keywords separated by semicolon (;)

Abstract: Insert an abstract under 200 words that describes the content of the contribution in a form suitable for inclusion in the meeting report as a summary of the content of the document, including a clear description of any proposals it may contain. See also Rec.A.2, clause I.1.2 for guidance.

Include some relevant Keywords, separated by a semicolon.

The Abstract field should contain a short summary of the document. It should not exceed 200 words and should be understandable by other SGs and readers. It should be generated AFTER the other sections are finalized.

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INTERNATIONAL TELECOMMUNICATIONS UNION
PREPARE THE TEXT OF THE CONTRIBUTION

Rationale (Discussion)

- Discussion, reason, and justification for the proposals.
- It develops the theme, describing the methods used, as well as the observations, findings, and comments on their significance.

Proposal (Conclusion)

- Most important part.
- Must indicate the intended disposition of the contribution.
- Distinction between *Proposals* and *Contributions.*

Supplement

- Supporting or more detailed information that would interrupt the flow of the main text.
- Solid line can be used to separate from the core text.
- Appendix, Annex, Supplement

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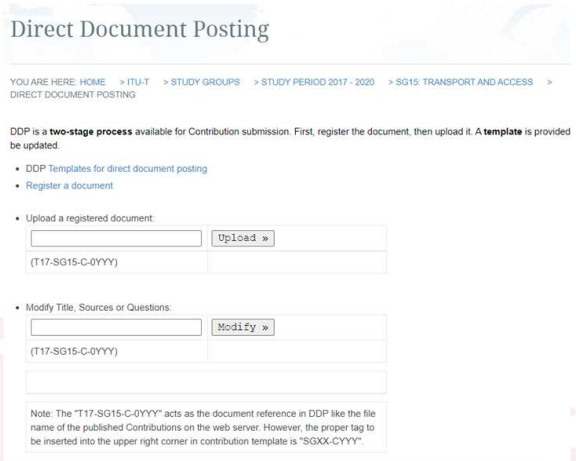
INTERNATIONAL TELECOMMUNICATIONS UNION
SUBMISSION


Direct Document Posting

YOU ARE HERE: HOME > ITU-T > STUDY GROUPS > STUDY PERIOD 2017 - 2020 > SG15: TRANSPORT AND ACCESS > DIRECT DOCUMENT POSTING

DDP is a **two-stage process** available for Contribution submission. First, register the document, then upload it. A **template** is provided be updated:

- DDP Templates for direct document posting
- Register a document
- Upload a registered document: Upload »
  (T17-SG15-C-0YYY)
- Modify Title, Sources or Questions: Modify »
  (T17-SG15-C-0YYY)

Note: The "T17-SG15-C-0YYY" acts as the document reference in DDP like the file name of the published Contributions on the web server. However, the proper tag to be inserted into the upper right corner in contribution template is "SGXX-CYYY".

Once ready, the contribution can be submitted by:

- Email
- Direct Document Posting system (https://www.itu.int/net/ITU-T/ddp/Default.aspx?groupid=T17-SG15)

After review and verification, it will appear on the SG's webpage under "Cs".

After the meeting, the proponent is called to present the contribution.

All contributions must be submitted 12 days before the meeting.

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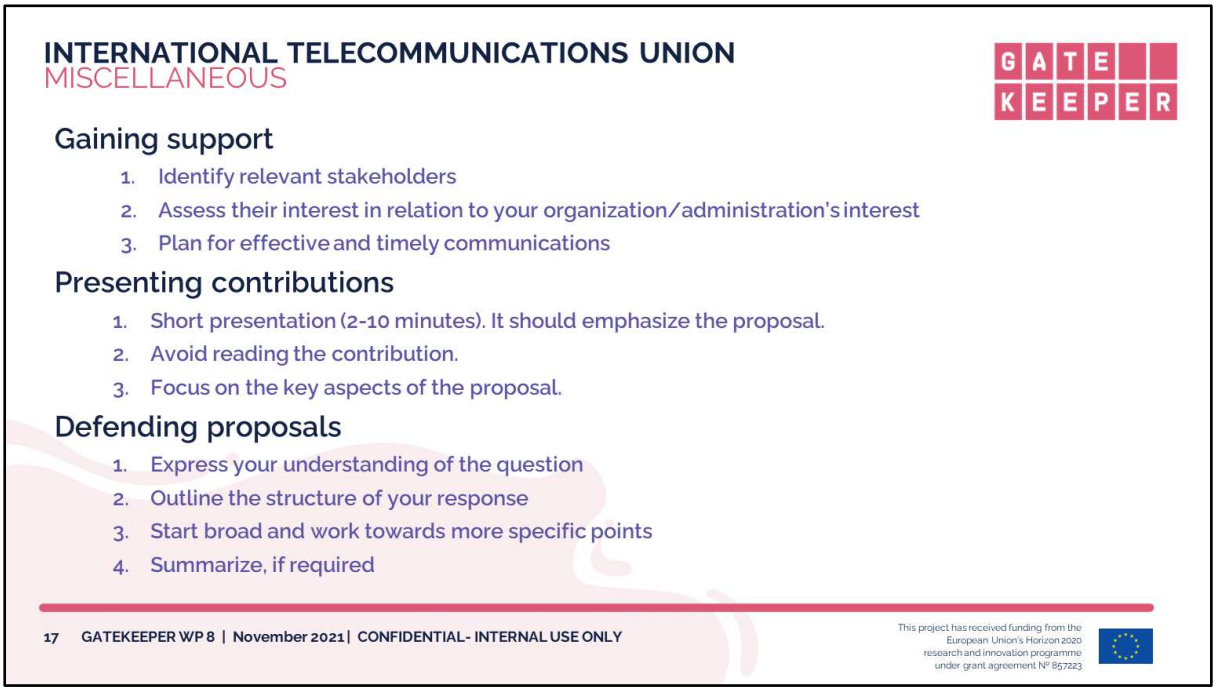

INTERNATIONAL TELECOMMUNICATIONS UNION
MISCELLANEOUS

GATEKEEPER

Gaining support

1. Identify relevant stakeholders
2. Assess their interest in relation to your organization/administration's interest
3. Plan for effective and timely communications

Presenting contributions

1. Short presentation (2-10 minutes). It should emphasize the proposal.
2. Avoid reading the contribution.
3. Focus on the key aspects of the proposal.

Defending proposals

1. Express your understanding of the question
2. Outline the structure of your response
3. Start broad and work towards more specific points
4. Summarize, if required

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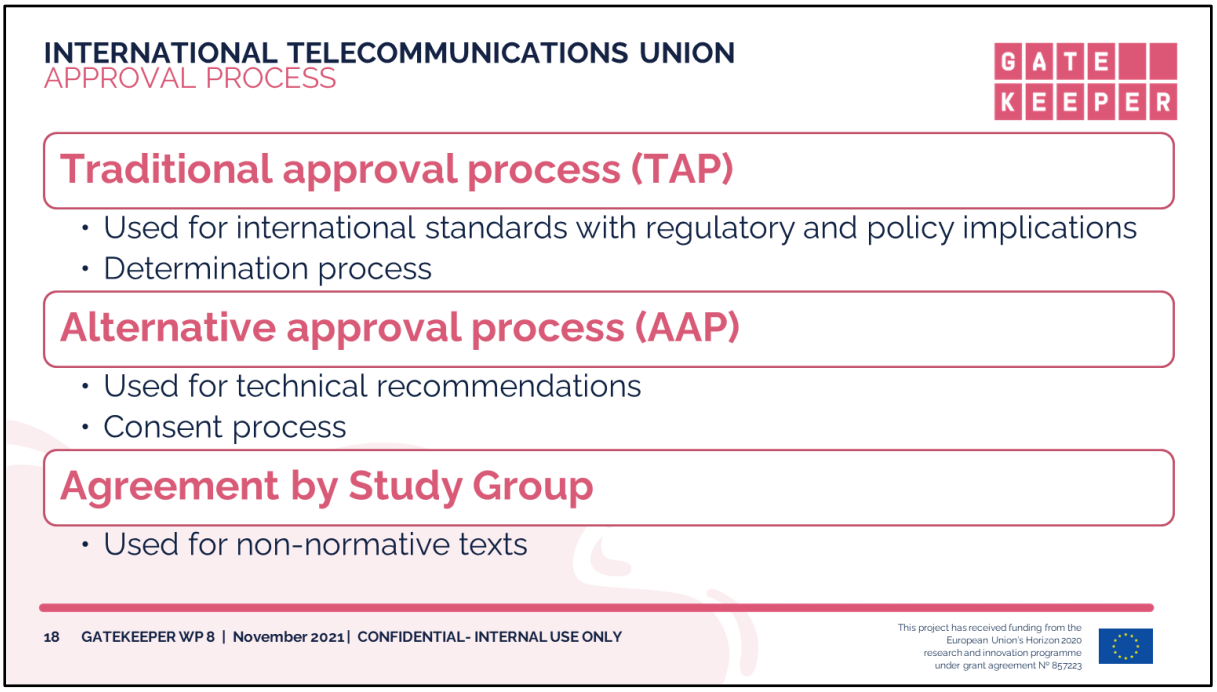

INTERNATIONAL TELECOMMUNICATIONS UNION
APPROVAL PROCESS

GATEKEEPER

Traditional approval process (TAP)

- Used for international standards with regulatory and policy implications
- Determination process

Alternative approval process (AAP)

- Used for technical recommendations
- Consent process

Agreement by Study Group

- Used for non-normative texts

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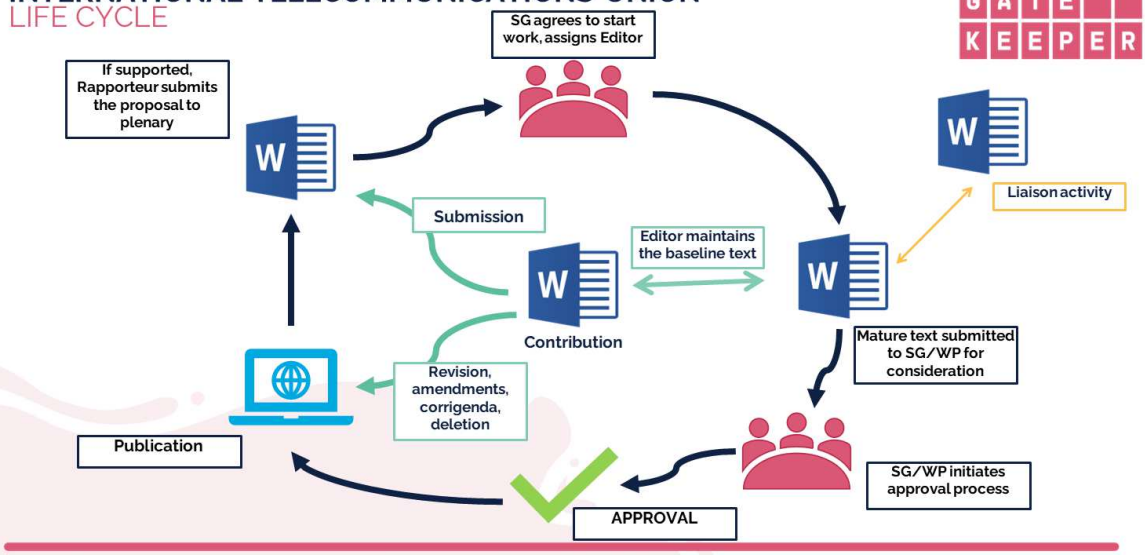
INTERNATIONAL TELECOMMUNICATIONS UNION
LIFE CYCLE



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INTERNATIONAL TELECOMMUNICATIONS UNION
RELEVANT RESOURCES

A.2: Presentation of contributions to the ITU Telecommunication Standardization Sector (https://www.itu.int/rec/T-REC-A.2)

Author's guide for drafting ITU-T Recommendations (https://www.itu.int/oth/T0A0F000004/en)

https://www.itu.int/en/about/Pages/default.aspx

https://www.itu.int/en/myitu/Membership

https://www.itu.int/en/ITU-T/membership/Pages/default.aspx

https://www.itu.int/en/mediacentre/backgrounders/Pages/itu-study-groups.aspx

https://www.itu.int/en/ITU-T/about/groups/Pages/tsag.aspx

https://www.itu.int/en/ITU-T/wtsa20/Pages/default.aspx

https://www.itu.int/en/ITU-D/Conferences/TDAG/Pages/TDAG20/Contributions.aspx

https://www.itu.int/en/ITU-T/studygroups/Pages/templates.aspx

https://www.itu.int/net/ITU-T/ddp/Default.aspx?groupid=T17-SG15

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INTERNATIONAL TELECOMMUNICATIONS UNION
CONTACT INFORMATION

Please do not hesitate to contact the team of Mandat International should you have any questions:

- Adrian Quesada Rodriguez (aquesada@mandint.org)
- Renáta Radócz (rradocz@mandint.org)

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HL7 INTERNATIONAL (HL7)

CATHERINE CHRONAKI
GIORGIO CANGIOLI
HL7 EUROPE

HL7 INTERNATIONAL
ABOUT

HL7 International

- not-for-profit, standards developing organization
- > 1,600 members from over 50 countries
- 500+ corporate members representing healthcare providers, government stakeholders, payers, pharmaceutical companies, vendors/suppliers, and consulting firms.

HL7 aims to provide standards that empower global health data interoperability.

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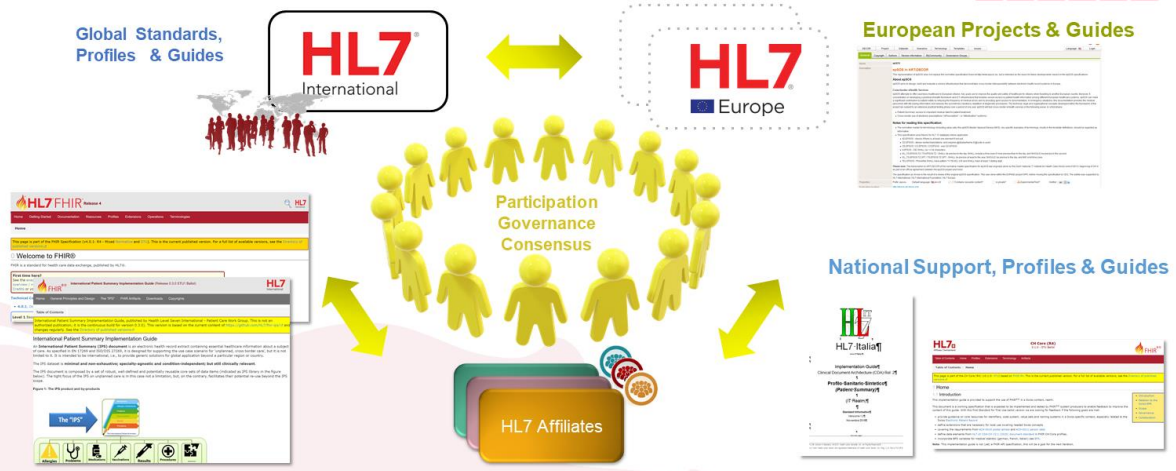
HL7 INTERNATIONAL
ABOUT



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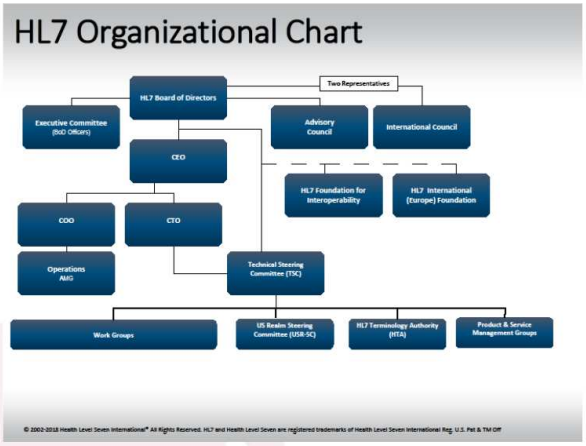
HL7 INTERNATIONAL
ORGANIZATIONAL CHART



About 40 WGs covering different areas of healthcare. Where the work is done !

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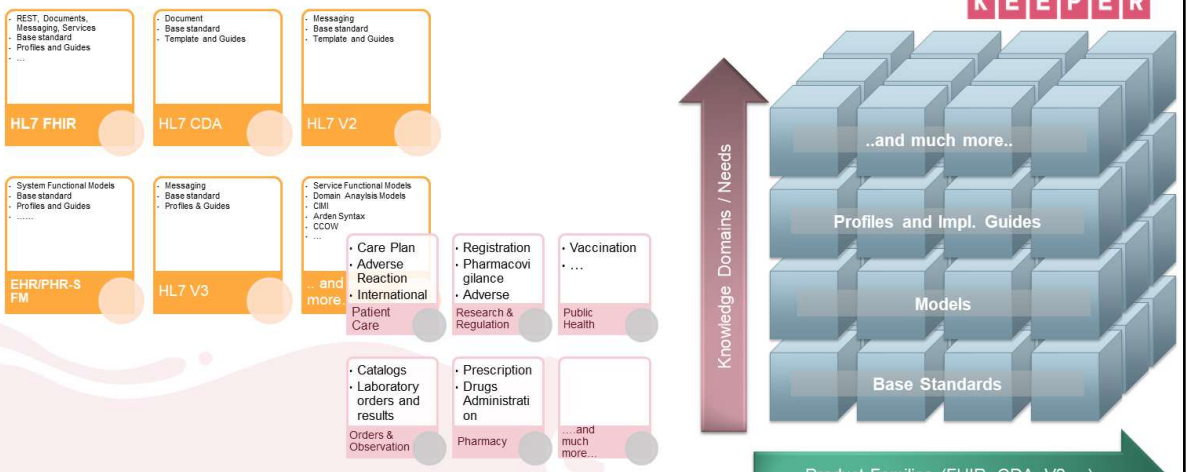
HL7 INTERNATIONAL
SEVERAL DOMAINS/PRODUCTS



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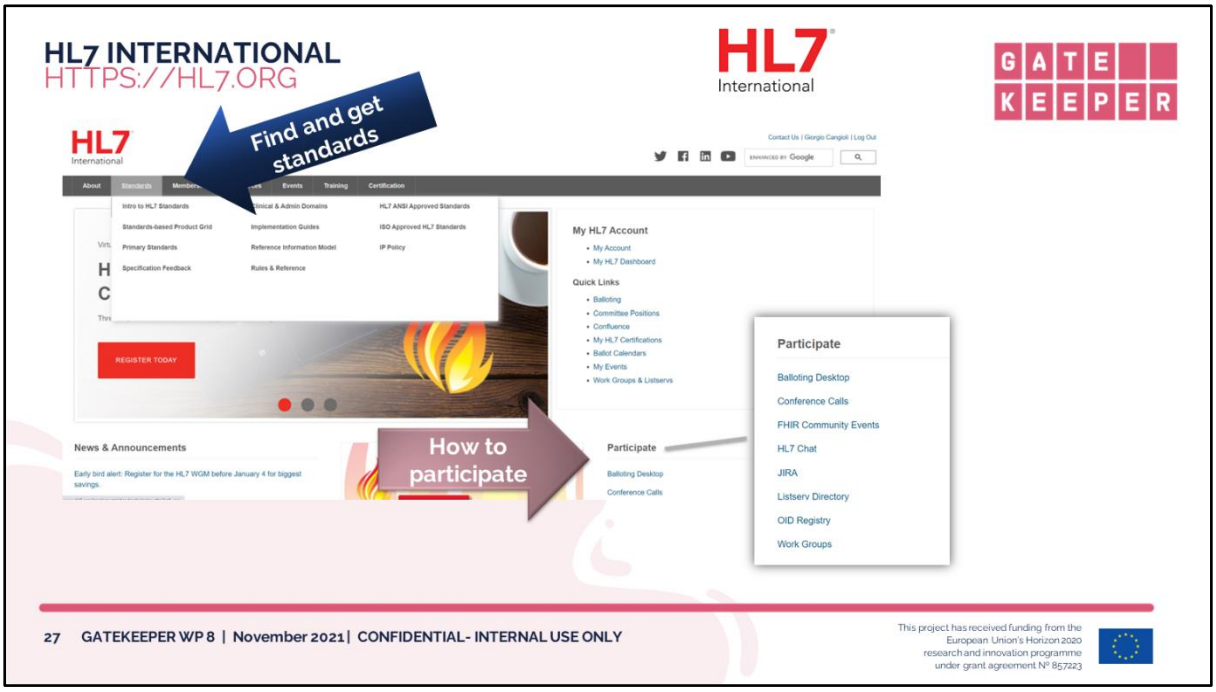
HL7 INTERNATIONAL
HTTPS://HL7.ORG
HL7 International
Find and get standards
How to participate
My HL7 Account
Quick Links
Participate
Balloting Desktop
Conference Calls
FHIR Community Events
HL7 Chat
JIRA
Listserv Directory
OID Registry
Work Groups
News & Announcements
27 GATEKEEPER WP 8 | November 2021| CONFIDENTIAL- INTERNAL USE ONLY
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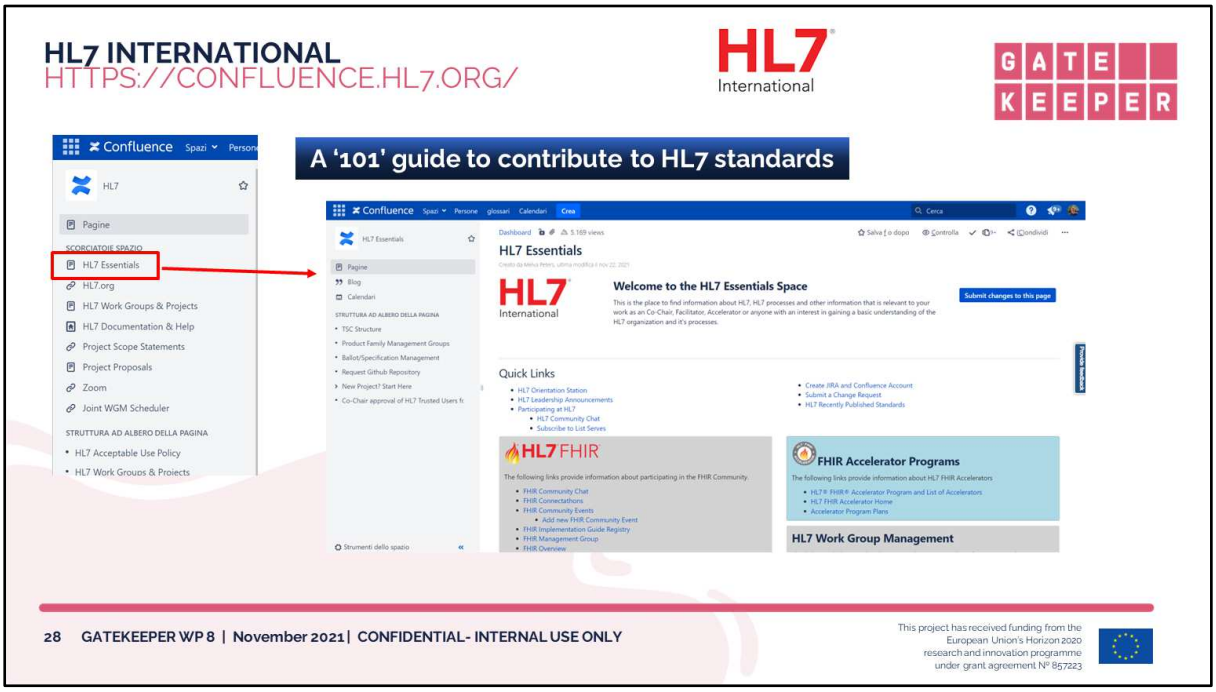
HL7 INTERNATIONAL
HTTPS://CONFLUENCE.HL7.ORG/
HL7 International
A '101' guide to contribute to HL7 standards
HL7 Essentials
Welcome to the HL7 Essentials Space
Quick Links
HL7 FHIR
FHIR Accelerator Programs
HL7 Work Group Management
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HL7 INTERNATIONAL
HOW IT WORKS

HL7 International

GATEKEEPER

Contributions

- Different ways to contribute
- Everyone can do it !

	Comment a published standard.	Propose a new standard /new version	Contribute to a standard development
Informal community discussion	Suggested	Suggested	Suggested
Start a new project	N/A	Required	N/A
Join project/WG meetings	Recommended	Part of the project life cycle	Required
Commenting	Required	Ballot comments are part of the project life cycle.	Optional

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HL7 INTERNATIONAL
HOW IT WORKS

Informal community discussion

GATEKEEPER

- **Share ideas and experiences, build consensus within the HL7 community/ies**
- **HL7 communities are open to member and non-members**

Meet community members virtually or in person at the **HL7 WGM meetings** or **FHIR Connectathon**

Participating in the HL7's community **discussion forum** as http://chat.fhir.org

Joining one of the HL7 **mailing lists** (https://www.hl7.org/myhl7/managelistservs.cfm)

Commenting /contributing through the HL7 projects **confluence** pages (https://confluence.hl7.org/)

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HL7 INTERNATIONAL
HOW IT WORKS

Contributions

- Different ways to contribute
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Commenting	Required	Ballot comments are part of the project life cycle.	Optional

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HL7 INTERNATIONAL
HOW IT WORKS

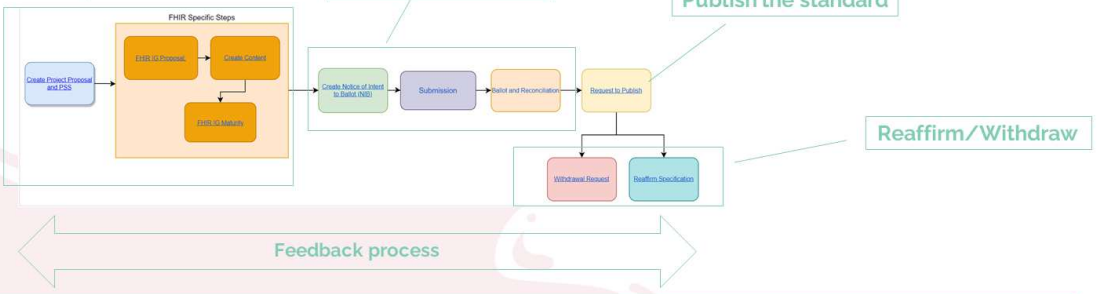
Start a new project

Create of a project proposal and then of a Project scope statement (PSS)

More infos:
https://confluence.hl7.org/pages/viewpage.action?pageId=111117149

Ballot the standard

Publish the standard



Reaffirm/Withdraw

Feedback process

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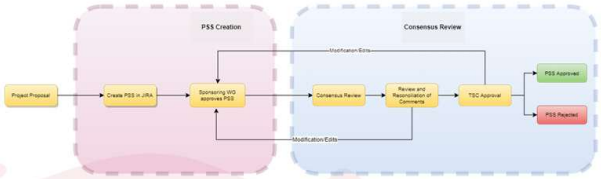
HL7 INTERNATIONAL
HOW IT WORKS: PROJECT PROPOSAL AND PSS

https://confluence.hl7.org/display/HL7/How+to+Create+and+Review+a+Project+Proposal



https://confluence.hl7.org/display/HL7/How+to+Create+a+Project+Scope+Statement+in+JIRA

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HL7 INTERNATIONAL
HOW IT WORKS

Contributions

- Different ways to contribute
- Everyone can do it !

	Comment a published standard.	Propose a new standard /new version	Contribute to a standard development
Informal community discussion	Suggested	Suggested	Suggested
Start a new project	N/A	Required	N/A
Join project/WG meetings	Recommended	Part of the project life cycle	Required
Commenting	Required	Ballot comments are part of the project life cycle.	Optional

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HL7 INTERNATIONAL
HOW IT WORKS

Join project/WG meetings

- Project / WG meeting is the place where topics are discussed, and decisions are taken.
- To join a meeting of a particular work group
  - work group's page (http://www.hl7.org/special/committees)
  - sign up to their list serve or look for the next conference call time-slot.
- Each working group has a confluence space where you can find projects information, and the meeting agendas and minutes.
  - Confluence spaces are available here https://confluence.hl7.org/

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HL7 INTERNATIONAL
HOW IT WORKS

Contributions

- Different ways to contribute
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	Comment a published standard.	Propose a new standard /new version	Contribute to a standard development
Informal community discussion	Suggested	Suggested	Suggested
Start a new project	N/A	Required	N/A
Join project/WG meetings	Recommended	Part of the project life cycle	Required
Commenting	Required	Ballot comments are part of the project life cycle.	Optional

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HL7 INTERNATIONAL
HOW IT WORKS

Commenting

Receiving and managing feedback from the community is an essential part of the HL7 standards development process

Specification Feedback

Ballot Comments

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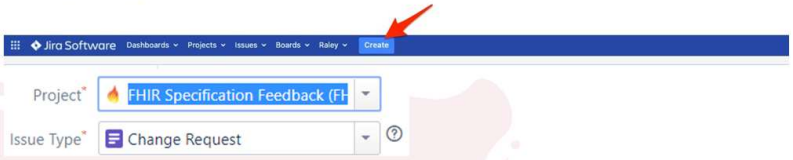
HL7 INTERNATIONAL
HOW IT WORKS

Specification Feedback

- Feedback might be suggesting a feature, pointing out a place where a specification is unclear or over-restrictive, identifying a spelling or grammar issue or suggesting that an entire area needs to be rethought.
- feedback can be submitted by at any time by anyone - even if they're not an HL7 member.
- In order to submit feedback, you must register as a user on HL7's Confluence and Jira systems.
- Feedback can be initiated by clicking on the "Create" button from http://jira.hl7.org, or in some cases, by using a link within an HL7-published specification.



Instructions: https://confluence.hl7.org/display/HL7/Specification+Feedback

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HL7 INTERNATIONAL
HOW IT WORKS

Ballot Comments

- Balloting is the **formal process** that HL7 uses to get feedback and comments on specifications prior to publication
- Membership is also necessary to be able to participate in
- Non-members who are members of certain other standards organizations may be entitled to reciprocal voting rights, but otherwise non-members must pay a fee for each specification they wish to vote on.

- Starting in January 2022, all ballots except Reaffirmation and Withdrawal Ballots will be done using Jira Balloting. Details on this process are given in the https://confluence.hl7.org/display/HL7/Jira+Ballot+Process page

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INTERNATIONAL TELECOMMUNICATIONS UNION
CONTACT INFORMATION

Please do not hesitate to contact the team of HL7 Europe should you have any questions:

- Catherine Chronaki (chronaki@hl7europe.org)
- Giorgio Cangioli (giorgio.cangioli@hl7europe.org)

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Annex III: Standardisation Contribution Plan

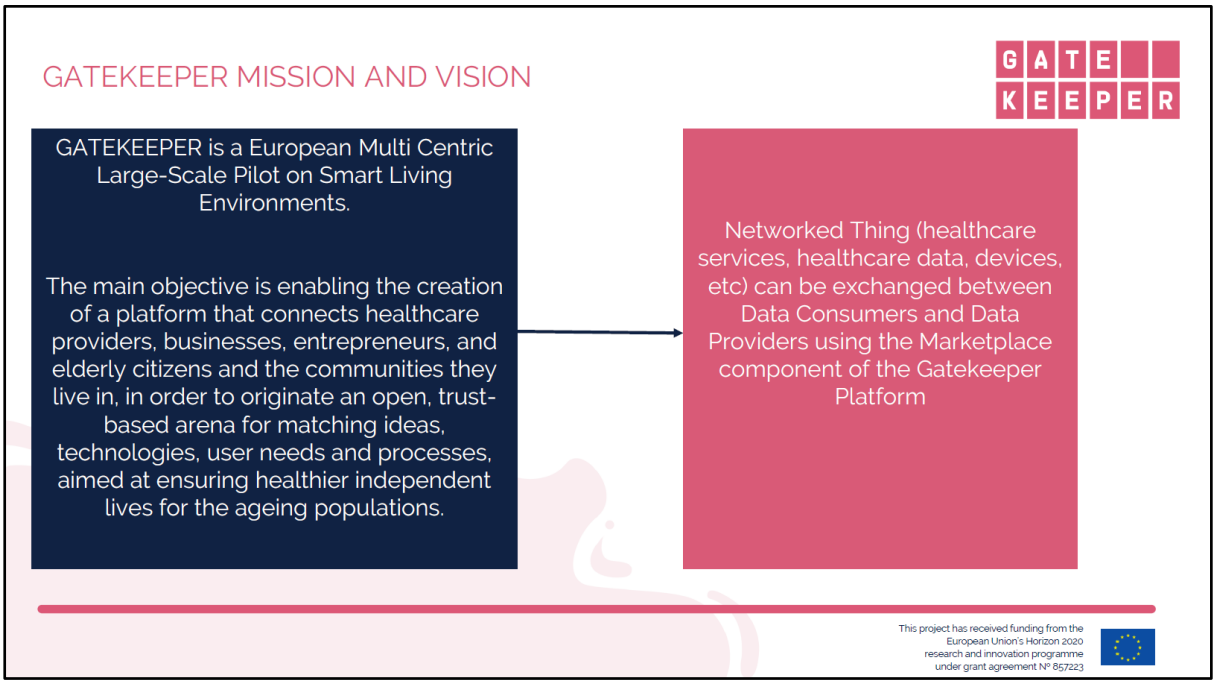
No.	WHAT			WHERE	WHEN	WHO	STATUS
	Contribution	Type					
Approved contributions							
1	Europrivacy Complementary Contextual Checks and Controls on eHealth	Technical	**Joint**	ECCP	**Oct 2022**	**MI, UDGA**	**DONE** Criteria included as an extension; approved by the Europrivacy International Board of Experts, the Luxembourgish Data Protection Authority, and EDPB as the first European Data Protection Seal.
2	Chunk graphs & rules	Technical	**Individual**	W3C	**Dec 2021**	**ERCIM**	**DONE** Community Group Report **https://w3c.github.io/cogai/** **https://www.w3.org/community/cogai/**
3	Alignment of Gatekeeper Trust Authority with IDSA architecture, specifically IDSA Clearing House and IDSA Dynamic Attribute Provisioning, and standards' validation	Presentation	**Individual**	ICT Verticals and Horizontals for Blockchain Standardisation, EC TEAMS (GRP-Blockchain Standardisation Channel	**Feb 2020**	**CERTH**	**DONE** 10 February 2021 on 9:00-12:30

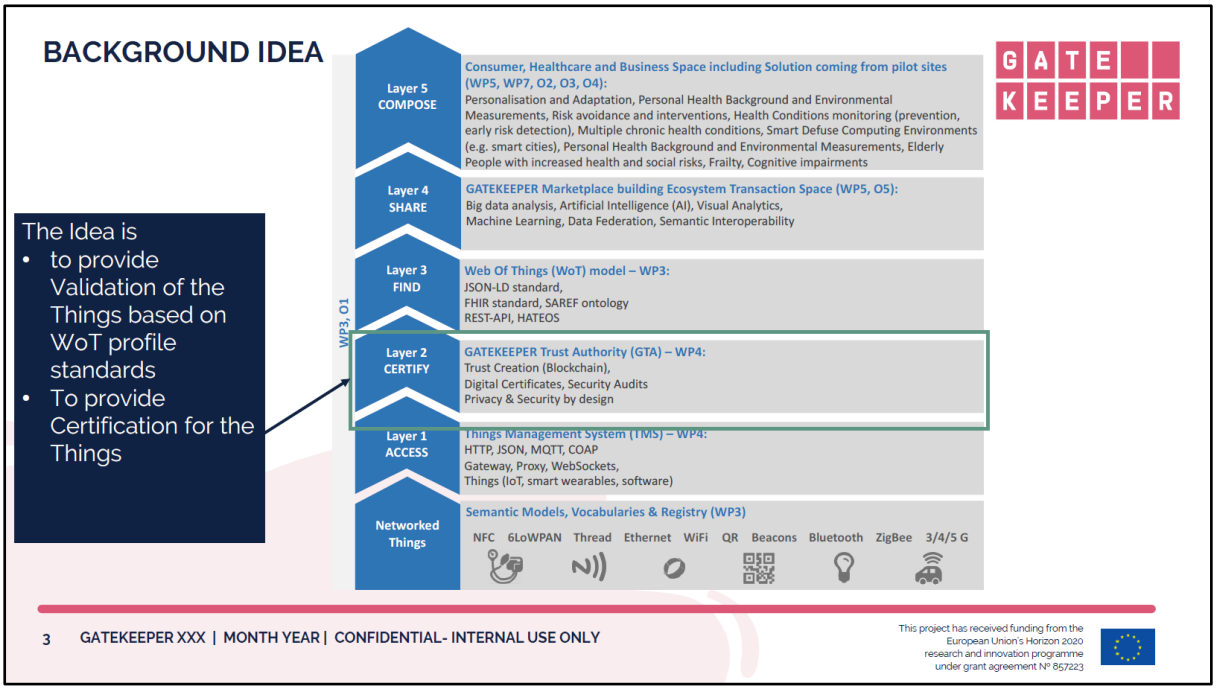
4	Skills that CERTH can deliver to IDS-based use cases as an implementation partner	Participation in event	**Individual**	IDSA Implementation Partner Workshop, IDSA	**March 2021**	**CERTH**	**DONE** 22 March 2021, 11:00–12:00
5	HL7 and SNOMED standards contribution	Technical	**Individual**	HL7 and SNOMED	**Not dated**	**HL7**	**DONE**
6	Overall project approach	Informative	**Joint**	ITU-T	**July 2022**	**MI/CIBER/Open Evidence**	**DONE** Submitted 5 July 2022, presented 20 July 2022
7	HL7 EU update on THE GATEKEEPER Project	Informative	**Individual**	HL7	**September 2022**	**HL7**	**DONE** Presented 21 September 2022 in Baltimore, USA
8	HL7 FHIR Implementation guide for Health Activities: how can we support the EHDS?	Informative	**Individual**	EFMI MIE	**May 2023**	**HL7**	**DONE** Presented at the EFMI MIE Conference 22-25 May 2023
9	Data Space Radar	Technical	**Joint**	IDSA	**July 2023**	**CERTH + All partners**	**DONE** https://internationaldataspaces.org/adopt/data-space-radar/

10	FHIR Implementation Guide (GK FHIR IG) for the certification of FHIR resources	Technical	**Individual**	HL7		**HL7**	**DONE** https://build.fhir.org/ig/gatekeeper-project/gk-fhir-ig/
In progress contributions							
1	Translator Web Of Things description to OpenAPI description with JSON-LD context	Technical	**Individual**	W3C/GitHub	**TBD**	**UPM**	**Confirmed** Demo in progress
2	TBD	TBD	**TBD**	TBD	**TBD**	**FUNKA**	**Confirmed** Drafting in progress
3	Standard on AI	TBD	**TBD**	TBD		**WP5/WP6**	**Not confirmed** To be discussed with AI Task Force in January
4	GATEKEEPER update	Informative	**Joint**	ITU-T	**July 2024**	**MI**	**Confirmed** Drafting in progress based on project final results
Abandoned contributions							
1	IoT Week invitation and session plan	Informative	**Individual**	ITU-T	**NA**	**MI**	**Abandoned**
2	Intervention process modelling	Informative	**Joint**	BPM+		**UPM/MED/WAR**	**Abandoned**

Annex IV: Contributions – additional material

A.1 Alignment of Gatekeeper Trust Authority with IDSA architecture




BACKGROUND IDEA
The Idea is
• to provide Validation of the Things based on WoT profile standards
• To provide Certification for the Things
Layer 5 COMPOSE
Consumer, Healthcare and Business Space including Solution coming from pilot sites (WP5, WP7, O2, O3, O4):
Personalisation and Adaptation, Personal Health Background and Environmental Measurements, Risk avoidance and interventions, Health Conditions monitoring (prevention, early risk detection), Multiple chronic health conditions, Smart Defuse Computing Environments (e.g. smart cities), Personal Health Background and Environmental Measurements, Elderly People with increased health and social risks, Frailty, Cognitive impairments
Layer 4 SHARE
GATEKEEPER Marketplace building Ecosystem Transaction Space (WP5, O5):
Big data analysis, Artificial Intelligence (AI), Visual Analytics, Machine Learning, Data Federation, Semantic Interoperability
Layer 3 FIND
Web Of Things (WoT) model – WP3:
JSON-LD standard, FHIR standard, SAREF ontology
REST-API, HATEOS
WP3, O1
Layer 2 CERTIFY
GATEKEEPER Trust Authority (GTA) – WP4:
Trust Creation (Blockchain), Digital Certificates, Security Audits
Privacy & Security by design
Layer 1 ACCESS
Things Management System (TMS) – WP4:
HTTP, JSON, MQTT, COAP
Gateway, Proxy, WebSockets, Things (IoT, smart wearables, software)
Networked Things
Semantic Models, Vocabularies & Registry (WP3)
NFC 6LoWPAN Thread Ethernet WiFi QR Beacons Bluetooth ZigBee 3/4/5 G
3 GATEKEEPER XXX | MONTH YEAR | CONFIDENTIAL- INTERNAL USE ONLY
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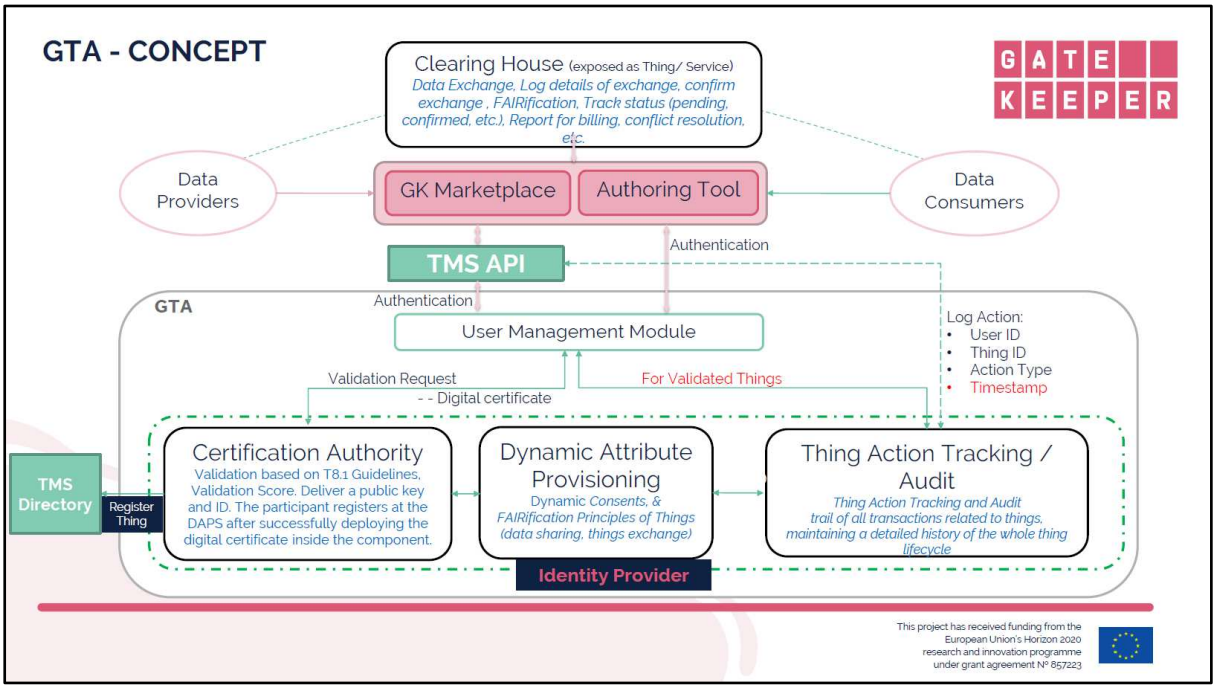
GTA - CONCEPT
Clearing House (exposed as Thing/ Service)
Data Exchange, Log details of exchange, confirm exchange , FAIRification, Track status (pending, confirmed, etc.), Report for billing, conflict resolution, etc.
Data Providers
GK Marketplace
Authoring Tool
Data Consumers
TMS API
Authentication
Authentication
GTA
User Management Module
Log Action:
• User ID
• Thing ID
• Action Type
• Timestamp
Validation Request
- - Digital certificate
For Validated Things
TMS Directory
Register Thing
Certification Authority
Validation based on T8.1 Guidelines, Validation Score. Deliver a public key and ID. The participant registers at the DAPS after successfully deploying the digital certificate inside the component.
Dynamic Attribute Provisioning
Dynamic Consents, & FAIRification Principles of Things (data sharing, things exchange)
Thing Action Tracking / Audit
Thing Action Tracking and Audit trail of all transactions related to things, maintaining a detailed history of the whole thing lifecycle
Identity Provider
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SUPPORTED USE CASES

- **UC1: REGISTER NEW THING**
  A Thing Provider wants to register a new Thing to the Platform
- **UC2: CONSUME EXISTING THING**
  A Thing Consumer searches and downloads an existing Thing

- Thing is **Validated** according to Technical and Scientific Standards
- Thing is **Certified** using the Blockchain-based Certification Authority

Logging of the Action is done to ensure
- Auditability
- Traceability
- Non-repudiation

7 GATEKEEPER XXX | MONTH YEAR | CONFIDENTIAL- INTERNAL USE ONLY

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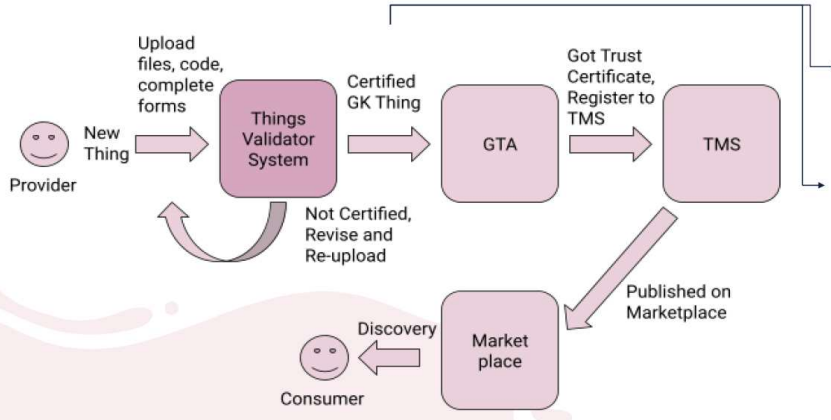
TECHNICAL , SCIENTIFIC, STANDARDS FOR THING VALIDATION

General Use Case Scenario Workflow



Automated for structure based validation (Technical_)\

Semi-Automated for non - structure based validation (Scientific and Standards_)\

A validation committee is established to support the semi-manual validation

8 GATEKEEPER XXX | MONTH YEAR | CONFIDENTIAL- INTERNAL USE ONLY

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TECHNICAL , SCIENTIFIC, STANDARDS THINGS VALIDATION

Standard	Applied To	Required Input from the Provider	Means to Validate	Outcome
W3C WoT	Things/Services	Thing Description	W3C Validator	W3C WoT Certified
HL7 FHIR	Things/Services	FHIR Description	FHIR Validator from https://www.hl7.org/fhir/validation.html (Runs locally/internally)	FHIR Certified
Gatekeeper Data Model	Things/Services	Data Model Description	Data Federation Validation/Integration	GK Data Model compliant
CE Mark	Biomedical Devices	Specification, Certification	Approve by Validation Consortium	CE Mark Certification Approved
ISO/IEEE 11073 Personal Health Device Standards	Biomedical Devices	Specification	Approve by Validation Consortium	Certification Approved
ISO 27000 series of information security standards	Things/Services and Biomedical Devices	This is a family of standards on information security. For the validation	Approve by Validation Consortium	Certification Approved

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HYPERLEDGER FABRIC ARCHITECTURE TO PROVIDE THINGS CERTIFICATION

Peer is a blockchain node that stores all transactions on a joining channel.

Orderer is a service responsible for ordering transactions, creating a new block of ordered transactions, and distributing a newly created block to all peers on a relevant channel

Certificate Authority or *CA* is responsible for managing user certificates such as user registration, user enrollment, user revocation, etc.

- Uses X.509 standard certificates

Client is considered to be an application that interacts with Fabric blockchain network

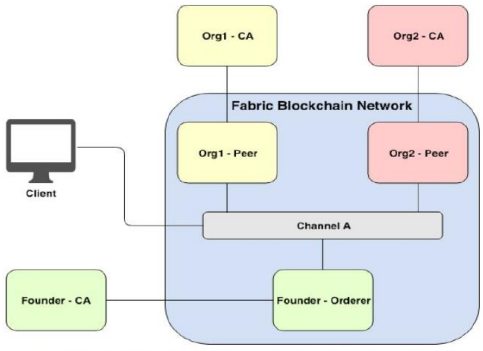

Figure 1. Simplest Fabric network with two organizations joining the same channel

Image taken from: https://medium.com/coinmonks/demystifying-hyperledger-fabric-1-3-fabric-architecture-a2fdb587f6cb

10 MEETING

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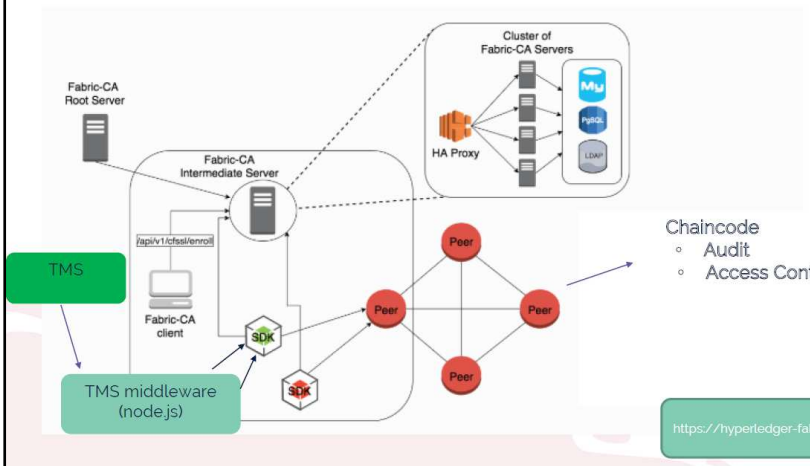
GTA COMPONENTS INTERACTION – THINGS CERTIFICATION



Explore connection with

- Fabric Certificate Authority (CA)
- Other Trusted CAs
- Alignment with IDSA

Chaincode
- Audit
- Access Control

Image taken from https://hyperledger-fabric-ca.readthedocs.io/en/release-1.4/users-guide.html

11 MEETING

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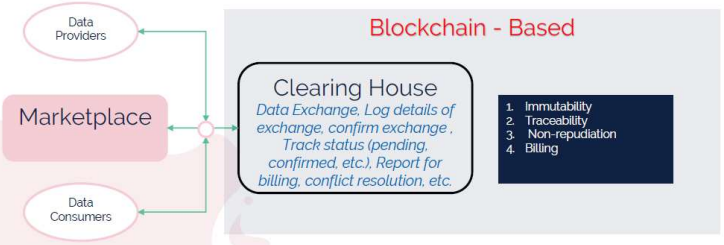
GTA~IDSA
CLEARING HOUSE

The Clearing House logs all activities performed in the course of a data exchange. After a data exchange, or parts of it, has been completed, both the Data Provider and the Data Consumer confirm the data transfer by logging the details of the transaction at the Clearing House. Based on this logging information, the transaction can then be billed. The logging information can also be used to resolve conflicts (e.g., to clarify whether a data package has been received by the Data Consumer or not). The Clearing House also provides reports on the performed (logged) transactions for billing, conflict resolution, etc.



12

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A.2 Overall project approach – International Telecommunications Union

INTERNATIONAL TELECOMMUNICATION UNION

TELECOMMUNICATION STANDARDIZATION SECTOR

STUDY PERIOD 2022-2024

SG20-C0099

STUDY GROUP 20

Original: English

Question(s): 5 Geneva, 05.07.2022

Source:	Mandat International	
Title:	H2020-857223 – GATEKEEPER	
Purpose:	Discussion	
Contact:	Sébastien Ziegler Mandat International Switzerland	Tel: +41 79 750 53 83 E-mail: sziegler@mandint.org
Contact:	Adrian Quesada Rodriguez Mandat International Switzerland	E-mail: aquesada@mandint.org
Contact:	Renáta Radócz Mandat International Switzerland	E-mail: rradocz@mandint.org
Contact:	Frans Folkvord Open Evidence Spain	E-mail: ffolkvord@predictby.com
Contact:	Jordi de Batlle Centro De Investigación Biomédico En Red Spain	E-mail: jdebattle@irblleida.cat
Contact:	Robin Kleiner Medisanté Group Switzerland	E-mail: robin.kleiner@medisante-group.com

Keywords: eHealth, ageing, healthcare system, Artificial Intelligence for Health, interoperability, MAFEIP, direct cloud technology

Abstract: Sharing of information on eHealth European Research that could be relevant for the SG20 and the Focus Group on Artificial Intelligence for Health. This content is purely informative.

Perspectives on eHealth research and potential for standardisation

Following the trends of decreased mortality rates worldwide, the age distribution of the populations across societies has changed considerably. Without sufficient support, ageing populations face rapid declines in physical and mental capacity. Currently, numerous

developments are made in the research domain of eHealth, particularly leveraging on Artificial Intelligence and the Internet of Things to tackle the burdens of chronic diseases and their impact on the sustainability of ageing populations. In this context, various research projects have been launched globally to trial and validate digital solutions for early detection and intervention.

The global deployment and market adoption of such eHealth solutions are one of the key priorities of the industry and the European Commission, but the lack of harmonisation and security/personal data protection implications are still in the way in the standardisation of Artificial Intelligence of Health. International collaboration and alignment among key regions are essential to the facilitation of this process.

Therefore, the European Commission is funding several research projects on eHealth and Artificial Intelligence of Health in the context of Horizon 2020 and now the Horizon Europe research programme. These projects pave the way towards secure deployment scenarios involving the use of Artificial Intelligence.

More specifically, the Horizon 2020 European Research project GATEKEEPER ambitions to connect healthcare providers, businesses, entrepreneurs, elderly citizens and the communities they live in to generate an open, trust-based arena for exchanging ideas, technologies, user needs and processes to ensure healthier and independent living for the ageing populations.

GATEKEEPER ambitions to:

- Harness the next generation of healthcare and wellness innovations;
- Cover the whole care continuum for elderly citizens, including primary, secondary, and tertiary prevention, chronic diseases, and co-morbidities;
- “Fit-by-design” European regulations on data protection, consumer protection, and patient protection;
- Be subject to reliable certification processes:
- Support value generation through the deployment of advanced business models based on the VBHC paradigm.

Impact assessment and evaluation – using the MAFEIP tool

GATEKEEPER includes a large number of user groups being representative of the respective population stratification within each large-scale pilot in seven European countries (Germany, Greece, Italy, Poland, Spain, United Kingdom and Cyprus). Considering this context, the GATEKEEPER consortium is fully aware of the need to implement a participatory methodology, including several stakeholders, training individuals and groups that are working in the pilots of the project on experimental designs, the development of the Key Performance Indicators (KPIs), the exact measurements, cost-effectiveness and impact assessment, and the execution of the studies, in order to align all the steps that are needed to conduct a comprehensive impact assessment and cost-effectiveness evaluation. Within the GATEKEEPER project, several steps have been conducted to establish the experimental designs and KPIs together with the pilot sites in order to be able to assess the impact of the interventions and conduct the cost-effectiveness evaluation with the Monitoring and Assessment Framework for the European Innovation Partnership on Active and Healthy Ageing (MAFEIP) tool.

Designing a methodological sound evaluation framework with valid and reliable key performance indicators is necessary to effectively test the outcomes of digital solutions in the healthcare sector, taking into account methodological aspects, such as validity and reliability for the results. Subsequently, it provides the opportunity to conduct cost-effectiveness analyses

to support evidence-based decision-making processes for stakeholders using the MAFEIP tool. The main objective of the MAFEIP tool is to estimate the outcomes of social and technological innovations, by providing an *a priori* estimation or *post-hoc* assessment of the likelihood that interventions will achieve their anticipated impact. In addition, MAFEIP also helps to identify the drivers of an interventions' effectiveness or efficiency in order to guide further design, development or evaluation. Therefore, MAFEIP represents clear support in the GATEKEEPER project to the decision-making process for the impact assessment of health technologies. Given that healthcare costs are expected to continue increasing throughout the upcoming decades, it is now more urgent to have a clear understanding of which interventions and technological solutions are most effective and have the biggest impact, while also taking into account their relative costs, especially to reinforce the uptake of cost-effective solutions.

Direct cloud technology

GATEKEEPER is deploying technologies to help automating home data collection considering social determinant of health and technology literacy rate from patients. These parameters both are indeed highly relevant when thinking about standardisation for the deployment of technology in healthcare.

Today, there are several ways to collect patient vitals from home and making such data interoperable into other systems from the care teams:

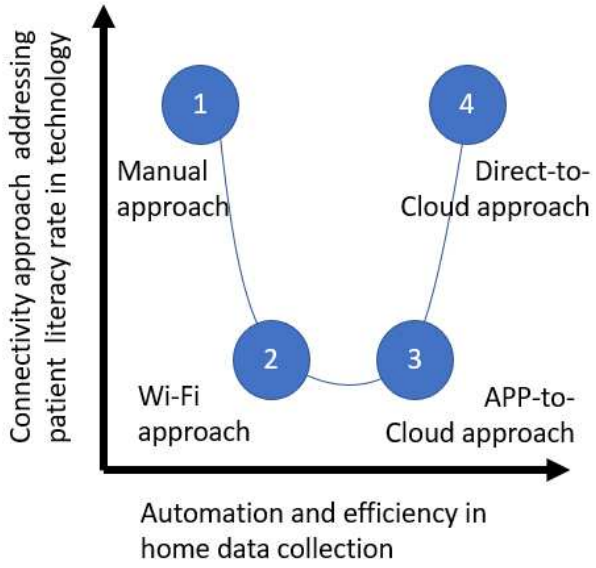


Figure 1 Approaches towards data collection

- *Manual approach*: manual realisation over a call, per post / fax or with a smartphone. It is hard to automate and often many steps are required for the users.
- *Wi-Fi approach*: automating via a WiFi connection for the medical devices. This assumes that patients can set the system themselves or that there is engineering support the technology deployment.
- *APP-to-cloud approach*: automating connection from smartphone to medical devices. This assumes again that patients are smartphone users and can maintain by themselves a connectivity infrastructure such as Bluetooth pairing.
- *Direct-to-Cloud technology*: this newest and latest approach foresees for large scale deployment of medical devices embedding SIM-cards in medical devices to send the

data on any software used by the care team. This is enabling data collection disregarding of patient inability to use connectivity technology such as smartphones and Bluetooth pairing.

The Direct-to-Cloud innovation consists of a SIM-card embedded into medical devices to make the device deployment simple, as shown in Table 1.

Table 1 Characteristics and advantages of Direct-to-Cloud technology

Characteristic	Advantages
Enables more interoperability to push data from devices into any health IT system on the screen of the doctor in almost real-time	Makes it easy for care teams to read vitals into their system in real time.
Reduces the dependency of smartphone into the connectivity architecture	Makes it easy for patients to connect with their doctors, disregarding the formers' technology literacy rate (i.e., zero configuration required) by enabling the SIM card to push information automatically.
Enables remote device management of devices	Makes it simple for the engineer to oversee in real time the device deployment and its technical attributes (e.g., device batteries, sync, etc.).
Enables the protection of patient information	Makes it simple for the data protection officer of *any* hospital to deal with patient information without requiring unveiling confidential patient information outside of the clinical systems. It only pushes device information, without collecting sensitive data.

Direct-to-cloud technology has already been recognised in the new continua guideline by the PCHalliance to automate reporting of home data to EHR systems [2]. With the deployment of the intelligent connected care services supported by Medisanté Group, GATEKEEPER is demonstrating how to simplify home data collection for any patients including the elderly without the ability to configure the connectivity with a mobile app, spreading a new standard in device interoperability.

This technology - SIM-card embedded in medical devices - will help care teams all around Europe to consider more confidently monitoring patients outside the hospitals. Similarly to IoT deployment in automotive or energy infrastructure, there is a high potential to leverage IoT technology in healthcare.

Many health IT systems are empowered with interoperability for seamless and automated home data collection. Plenty of hospital and regional clinics systems require simple access to home patient data. This new architecture enables the simple integration of device data into health IT servers pushing data through RESTful API. With the emergence of new horizons and demands, enabling additional capabilities in decentralised healthcare settings became crucial. An increasing number of players invest in moving firmware capabilities in the cloud with M2M communication at the level of large fleet of medical devices.

Additionally, the certification of IoT connectors must be considered for the further standardisation of medical IoT. Within GATEKEEPER, partners ensure CE-marking of IoT connectors by using embedded SIM-cards, demonstrating how innovative solutions can be deployed in the context of multiple help care teams and patients within 11 pilots and over 7 therapeutic areas.

Conclusion

Considering the fundamental nature of IoT connectivity and Artificial Intelligence in the eHealth domain, SG20 should closely follow up with the research developments in this domain and should consider addressing standardisation needs in the area in coordination with the Focus Group.

SG20 should also consider studying the eHealth domain and its impact on sustainable communities, especially in the upcoming study period. In doing so, reference to IoT interoperability and Artificial Intelligence for Health should be included in the Wording of the SG20 Questions that will be submitted to TSAF for first review and subsequent approval at WTSA-20.

Finally, GATEKEEPER is willing to share relevant results for standardisation with SG20 and the Focus Group.

References

[1] https://www.gatekeeper-project.eu/

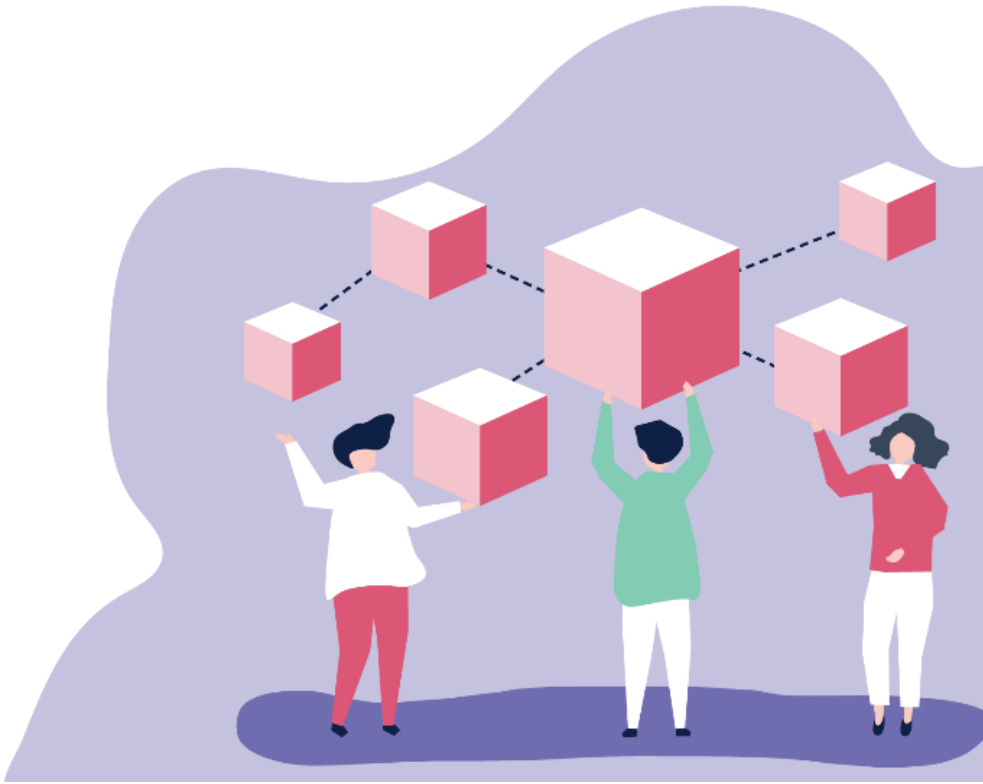
[2] https://www.pchalliance.org/news/new-continua-design-guidelines-support-health-home-targeting-direct-cloud-solutions

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement N° 857223

GATEKEEPER

D8.4 ANNEX I: Standardization report and recommendations

Description	This Annex seeks to support the Gatekeeper consortium in submitting meaningful contributions to standardization.		
Type	Other	**Dissemination Level**	CO
Work Package No.	WP8	**Work Package Title**	Standardization and certification mechanisms
Version	1.0	**Status**	Final



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History

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27/10/2021	0.1	Initial version ToC, format ITU procedure inclusion
12/11/2021	0.2	Integration of FUNKA feedback
07/12/2021	0.3	Integration of HL7 guideline Clearing of comments
12/12/2021	0.4	Integration of W3C and AIOTI guideline
26/01/2022	0.5	Integration of SN and CEN-CENELEC guidelines ToC update
03/02/2022	0.6	Elaboration of W3C guidelines
13/02/2024	1.0	Final version ready for submission

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Statement of originality

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1 Introduction

As part of WP8 actions on 'Standardization and certification mechanisms', the objective of T8.2 'GATEKEEPER platform standardization process and wide-spread adoption across Europe' is to coordinate standardization activities relevant to GATEKEEPER technologies, both on the European and global level. It aims to coordinate efforts around legal and privacy aspects, healthcare, ageing, cities and energies, Internet of Things (IoT), Big Data and other Key Enabling Technologies.

The objective of this Annex is to provide extensive guidelines and a list of templates/useful resources from consortium members active in Standards Development Organizations (SDOs) to members who wish to contribute to standardization activities.

1.1 ICT standardization roadmap

Benefiting both consumers and the industry, information and communication technologies (ICT) standards play a crucial role in achieving interoperability of new technologies. Standards are essential for ensuring competitiveness and they are brought forth by international and national bodies, as well as alliances. Some of the key ICT standardization bodies are included in the following figure:

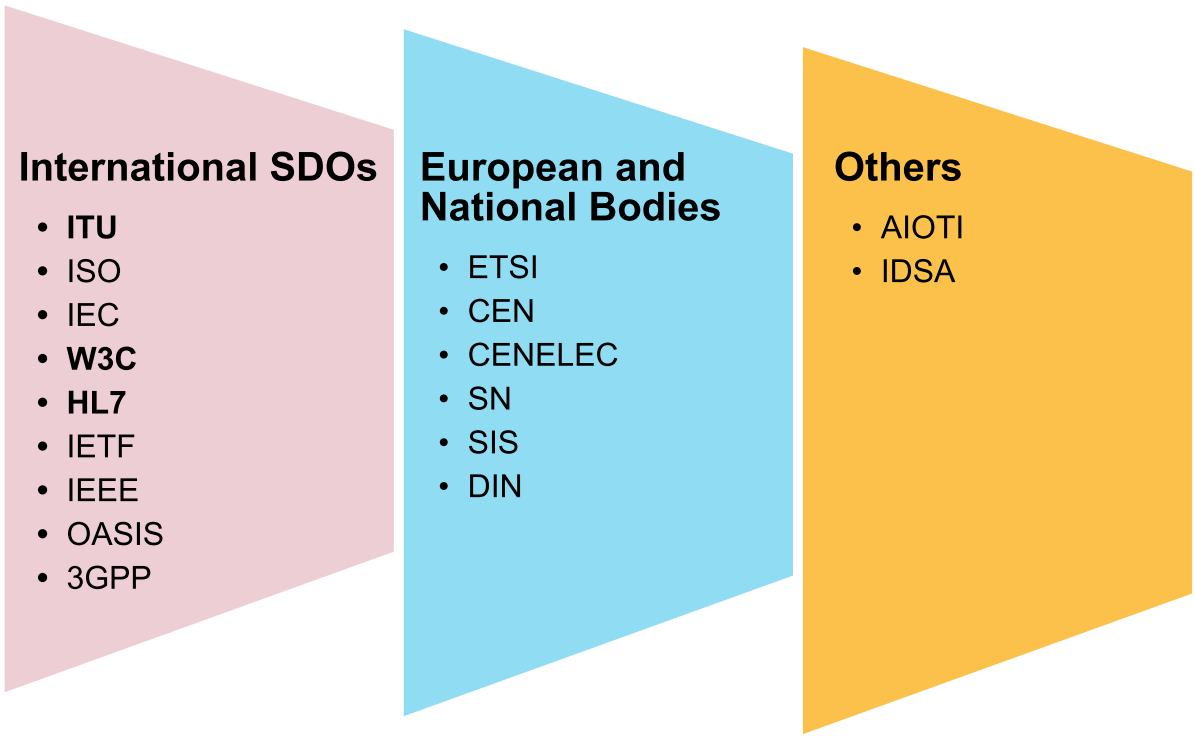

Figure 1 Standard bodies and alliances

1.2 Objective and methodology

The main objective of this Annex is to familiarize consortium members with standards development processes specific to the various target SDOs. It intends to provide synthetic yet detailed guidance on the contribution submission process specific to SDOs and includes a repository of reference templates to be used for preparing such contributions.

The document is structured into several sections. After the general introduction, the document introduces relevant Standards Development Organizations. Each respective section provides a general overview of these bodies, including how standards development processes work and how to submit contributions. The sections include useful templates, as well as the contact details of involved consortium members who can support the submission of contributions.

2 International Telecommunications Union

The following section introduces the role and working methods of the International Telecommunications Union (ITU)[1] and provides a detailed overview on how to submit contributions to the Telecommunication Standardization Sector (ITU-T).

2.1 About the ITU

The International Telecommunications Union plays a dual role within the United Nations (UN); it not only functions as the UN agency for information and communication technology but also as an international standards development organisation. It currently has 193 member states, as well as 700+ private sector and 150+ academia members.

The work of the ITU is divided into three sectors[2]. The ITU Radiocommunication (ITU-R) focuses on the coordination of radio-frequency spectrum and assigns orbital slots for satellites. The **ITU Standardization (ITU-T)** focuses on establishing global standards for telecommunications. Lastly, the ITU Development (ITU-D) focuses on bridging the digital divide for leveraging ICTs for sustainable development and transition to a circular economy. Keeping in mind the goal of the present document, the following section details how the ITU-T works.

2.1.1 About the ITU-T

The ITU-T[3] is a platform for governments and the private sector to coordinate the development of international standards (i.e., **ITU-T Recommendations**) for information and communication technologies. Its main objectives include:

1. **Development of standards**: developing non-discriminatory international standards to foster interoperability and improved performance of equipment, networks, services, and applications.
2. **Bridging the standardization gap**: promoting active participation of the members in the definition and adoption of standards to bridge the standardization gap.
3. **Telecommunication resources:** ensuring effective allocation and management of international telecommunication numbering, naming, addressing, and identification resources.
4. **Knowledge-sharing:** fostering the acquisition, awareness, and sharing of knowledge and know-how.
5. **Cooperation with SDOs**: extending and facilitating collaboration.

The following figure illustrates the structure of the ITU-T. The roles of each actor are presented later.

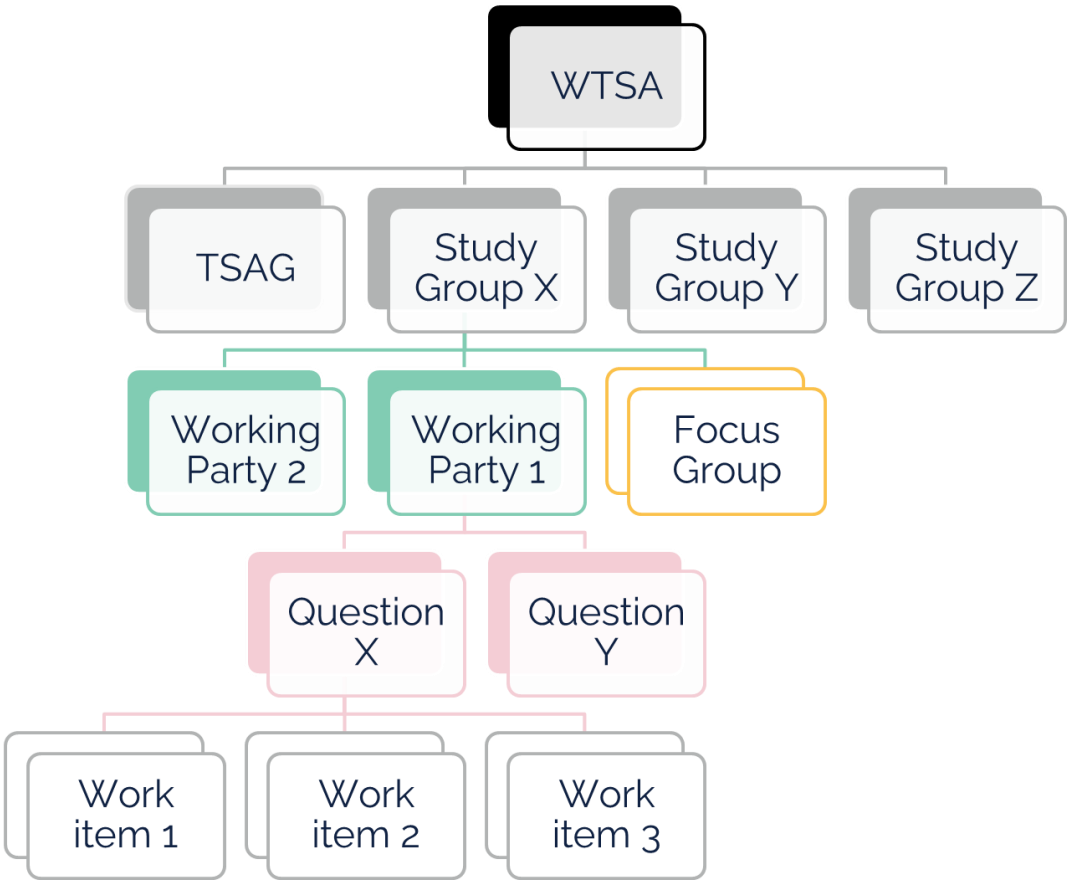

Figure 2 ITU-T Structure

2.1.1.1 ITU-T Study Groups

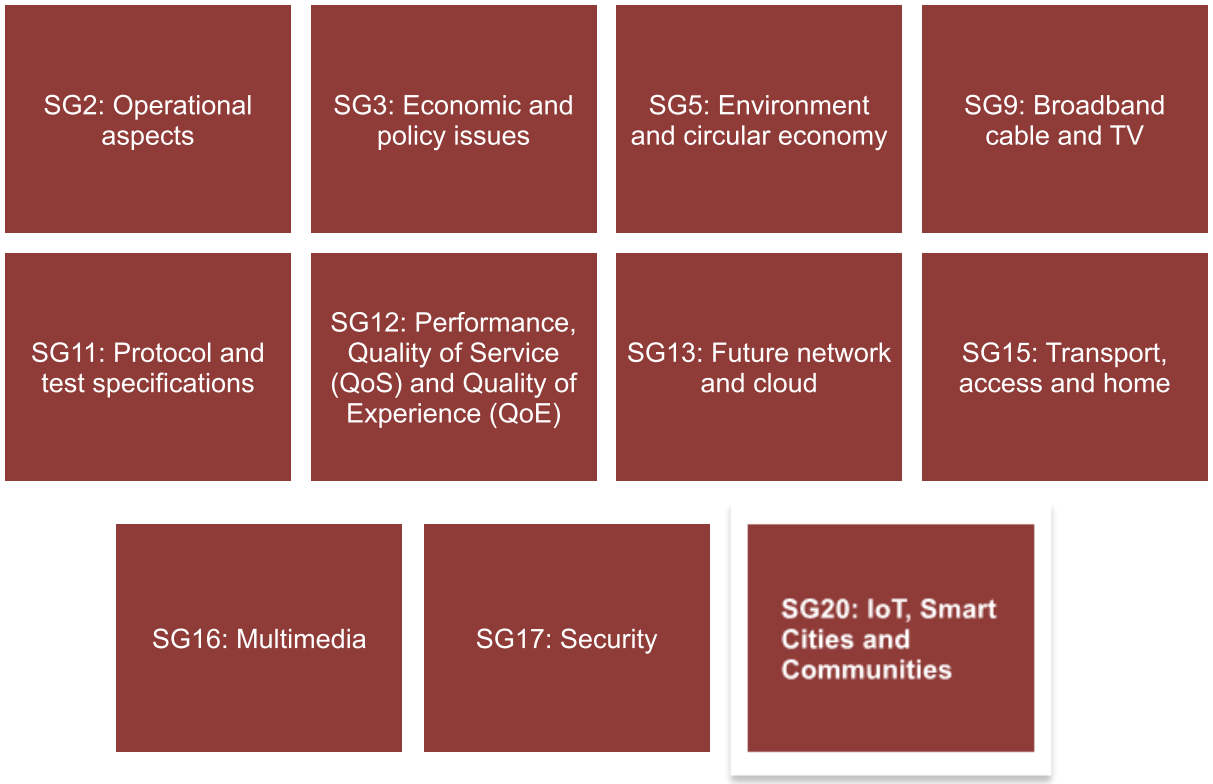

Figure 3 Active ITU-T Study Groups

The standardization work of the ITU-T is organized by **Study Groups (SG)**[4] that act as building blocks of the standardization process. Members of SGs develop ITU-T Recommendations for the various fields of international telecommunication on a consensus basis. Each SG has its own area of responsibility, leadership, and authority to initiate, develop, and propose ITU-T Recommendations. As noted in Figure 2, eleven SGs are currently active.

Study Groups contain one or more **working groups** that include Questions. **Questions** describe an area of work to be studied, normally leading to the production of new or revised Recommendations. A **Work Item** is an assigned piece that is identifiable with a Question and has a specific or general objective resulting in a product (e.g., the publication of a Recommendation). The **Work Programme** is a list of work items that are owned by an SG.

Each Study Group has a management team that is led by the **Study Group Chairman** and Vice Chairman who help to navigate the activities of the SG. The activities within each working party are overseen by the **Working Party Chairman** and Vice Chairman. **Rapporteurs** and Associate Rapporteurs oversee leading the work on Questions, while Editors are responsible for maintaining the text of relevant work items. Delegates attending the various ITU-T meetings represent a member state, sector members, or academic institutions. Liaison Rapporteurs help maintain the communication with other SGs or SDOs. On the Secretariat's side, the SG is supported by a counsellor, advisor, engineer, project officer, and/or an assistant.

2.1.1.2 Telecommunication Standardization Advisory Group (TSAG)

TSAG[5] reviews priorities, programmes, operations, financial matters, and strategies for the ITU-T. It also oversees the progress of the implementation of ITU-T's work program and provides guidelines for the work of the SGs. It also facilitates coordination with the other

sectors of the ITU, the General Secretariat, and other SDOs. Meetings take place every year.

2.1.1.3 World Telecommunication Standardization Assembly (WTSA)

WTSA[6] is the highest decision-making body of the ITU-T, overseeing standardization activities. Their meetings take place every four years setting the future trajectory of standardization work.

2.1.1.4 Focus Groups

Study Groups can create Focus Groups to advance the work of the ITU-T and to encourage the participation of experts who may not be ITU members. Focus Groups serve as an instrument to provide an additional working environment for the quick development of standards in specific areas.

2.1.2 Documents

2.1.2.1 Contributions

Contributions are submitted by Member States, Sector Members, Associates, and academia participants *in advance* of SG meetings. They are intended to move the work forward and usually address specific **Question**s of the given SG. The contributions are numbered sequentially within each SG.

2.1.2.2 Temporary Documents (TDs)

TDs are submitted by a meeting official (i.e., a member of the SG Management Team) or by the Secretariat. They can be posted before and during the meeting. TDs include reports generated during the meeting, latest draft text for Recommendations, inputs from other SGs or SDOs (i.e., liaison statements),

2.1.2.3 ITU-T Recommendations

ITU-T Recommendations (ITU-T Recs) are international standards defining how telecommunication networks operate and interwork. They have a non-mandatory status until adopted in national laws. Nevertheless, levels of compliance are high due to international applicability and the high quality guaranteed by the ITU-T and its members.

ITU-T Recommendations can contain an *Annex* (material that is necessary to the overall comprehensibility), an *Appendix* (material that is supplementary to the subject matter), and a *Supplement* (an informative non-normative document).

2.1.2.4 Technical Papers

Technical Papers contain non-normative information on various topics addressed by ITU-T SGs. They are available free of charge and involve small editorial overhead. They cover a diverse range of topics, including economy, policy, e-health, mobility, etc.

2.1.2.5 Liaison statements (LS)

Liaison statements sent to and from other bodies as information or questions transmitted. LS indicate the source of the statement, the body to which it is directed, and the action desired.

2.1.2.6 Collective Letters and Circulars

A Collective Letter contains invitation to a specific SG meeting, draft agenda, link to the meeting, etc. It can also include information on the Alternative Approval Procedure (AAP).

Circulars are issued for a variety of purposes, including information of general interest, announcement of workshops or approval/deletion of Recommendations.

In the context of Gatekeeper, we focus on submitting Contributions to the ITU-T SG20 following the two main objectives of developing of standards and the bridging of the standardization gap.

2.1.3 How to sign up

To be able to access the latest documents and to subscribe to a mailing list, interested parties must have a TIES Account. More information: https://www.itu.int/en/ties-services/Pages/default.aspx

In the context of the Gatekeeper standardization activities, partners interested in contributing to the ITU can also contact MI in order to obtain any required information.

2.2 The journey of a Contribution

Contributions[7] power the Study Groups, and they must be clearly written and well-structured as they are essential to the success of the SGs and WPs. International standards depend entirely on the timely submission of relevant, quality contributions. Contributions cover:

- Proposals for new work items;
- Inputs relevant for the SG's Questions or work items, including:
    - Proposals for new draft Recommendations
    - Draft Recommendation texts
    - Edits and changes to existing base texts
    - Support for other proposals;
- Proposals on the organization and working methods of the SG;
- Information or material relevant to the work of the SG.

2.2.1 Drafting and submitting a contribution

For faster processing and publishing, a template[8] has been prepared for delegates who wish to make a contribution to the ITU-T, in order to minimize formatting at the receiving end. In general, a contribution can be submitted following 4 steps:

2.2.1.1 Select meeting

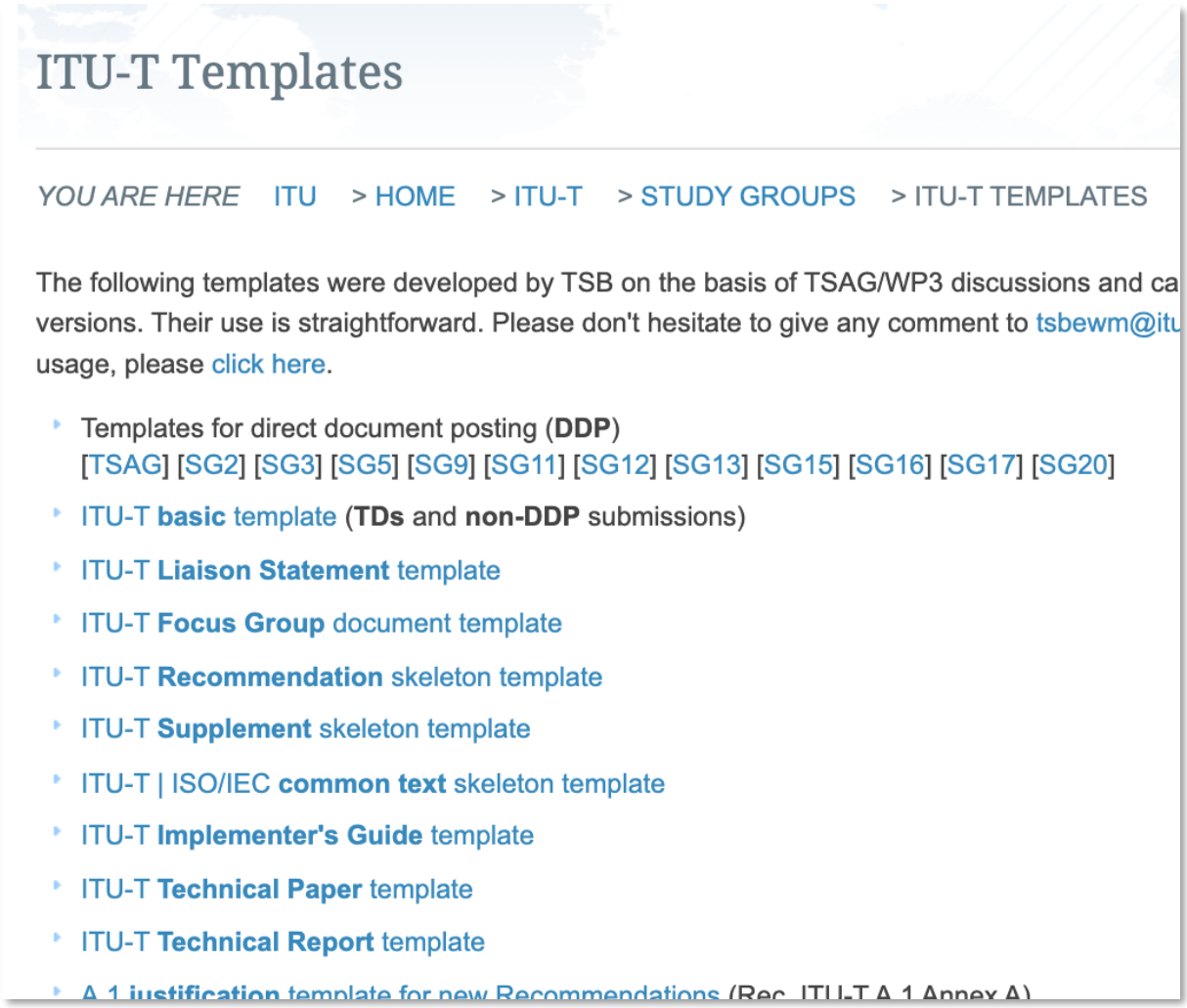

Figure 4 ITU-T Templates

1. Go to the ITU-T template webpage: https://www.itu.int/en/ITU-T/studygroups/Pages/templates.aspx
2. Select the Study Group of your interest (SG20)
3. Click and download the template

2.2.1.2 Fill in the requested administrative information

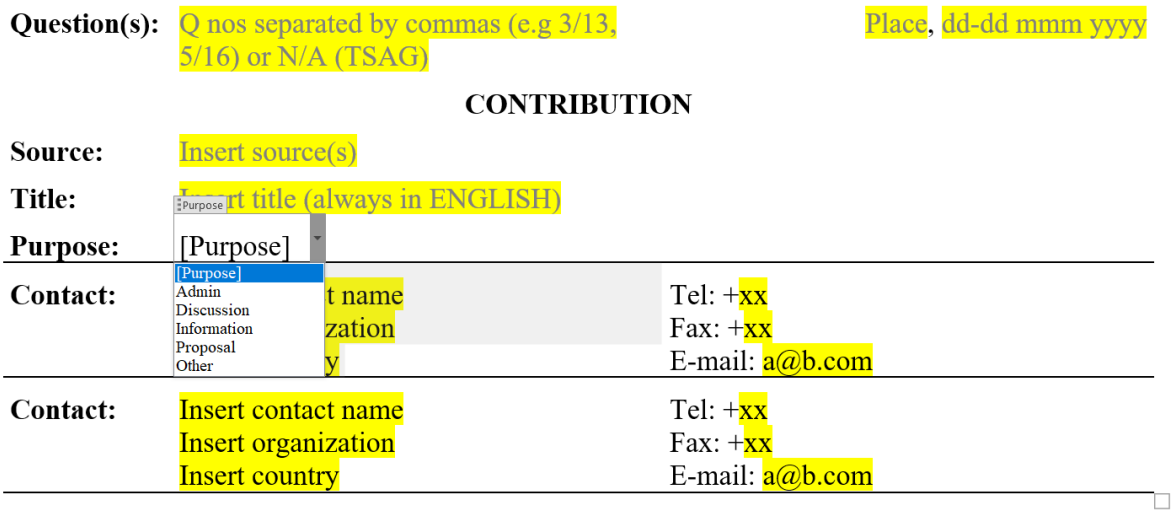

Figure 5 Requested description

At the **Source**, you need to indicate the entity which you will represent at the meeting.

Include the **Title** of the document in English. The title should not be unnecessarily long and should provide an indication of the main topics covered. The title should be unique and should not contain acronyms. It should not repeat the series and sub-series titles which are already indicated on the Recommendation cover page.

Define the **Purpose** of the document, depending on if the goal is an action or information.

Enter your **contact details** for the contribution. These details will be displayed in the footer of the final document.

Include some relevant **Keywords,** separated by a semicolon.

The **Abstract** should outline clearly and concisely the aim and the content of the document. In addition, it should enable prospective readers to determine quickly whether the contribution contains information in their area of interest and, often, which working party(ies) should review the contribution. An abstract should not exceed 200 words and should be understandable by other SGs and not just the intended readers of the contribution. Normally, it should be prepared AFTER other sections are written.

2.2.1.3 Provide the text of the contribution

After filling in the administrative details, the document must include the core text of the contribution. To avoid the reformatting of figures, tables, and other non-textual elements, the form must be uploaded in Word format.

The text of the contribution includes 2 key sections and one supplementary section, as applicable:

Rationale (Discussion)	Proposal (Conclusion)	Supplement
• Discussion, reason and justification for the proposals. • It develops the theme, describing the methods used, as well as the observations, findings and comments on their significance	• Most important part. • Must indicate the intended siposition of the contribution. • Distinction between **Proposals** and **Contributors**.	• Supporting or more detailed information that would interrupt the flow of the main text. • Solid line can be used to separate from the core text. • Appendix, Annex, Supplement

Figure 5

The *heading Proposal* should be used when the section offers suggestions for acceptance (such as solutions, plans and changes the contributor expects to be implemented) and when decisions or actions are requested. The *heading Conclusion* should be used when it is merely informational, such as summarizing observations and no decision about a course of action is expected. If both appear in a contribution, the proposals should follow the conclusions.

2.2.1.4 Submit

Once a contribution is ready, it can be submitted directly to the Secretariat by email or via the online Direct Document Posting (DDP) system[9]. Once the contribution is reviewed and verified, it will appear on the SG's webpage under "Cs" for contributions. At the meeting itself, the proponent of the contribution will be called upon to briefly present the contribution.

In principle, all contributions must be submitted **12 days** before the meeting. A contribution should be submitted at least **2 months** before the meeting if a translation is requested.

2.2.2 After submission

2.2.2.1 Gaining support

1. Identify relevant stakeholders
2. Assess their interest in relation to your organization/administration's interest
3. Plan for effective and timely communications

2.2.2.2 Presenting contributions

1. Short presentation (2-10 minutes). It should emphasize the proposal

2. Avoid reading the contribution
3. Focus on the key aspects of the proposal

2.2.2.3 Defending proposals

1. Express your understanding of the question
2. Outline the structure of your response
3. Start broad and work towards more specific points
4. Summarize, if required

2.2.2.4 Approval processes

1. **Traditional approval process (TAP)** is used for international standards (ITU-T Recs) with regulatory and policy implications. The draft recommendations go through the process called 'Determination' at the physical Study Group meeting, and is carried forth in consultation with member states.
2. **Alternative approval process (AAP)** is used for technical recommendations. It goes through a process called 'Consent' at the physical meeting, and an email notification of the AAP initiation is sent, as well as an online last call.
3. **Agreement by Study Group** is used for non-normative texts.

2.2.3 Work Item life cycle

The following figure summarizes the life cycle of Work Items at the ITU-T.

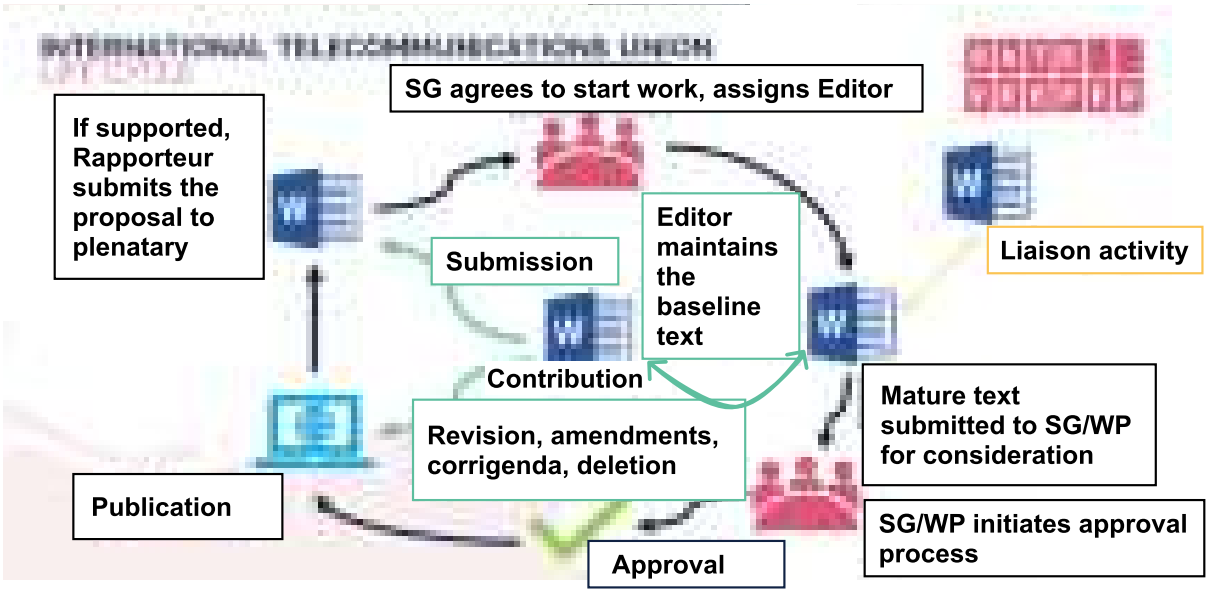

Figure 6 Work Item life cycle

After a member contribution is submitted, if supported by experts, a Rapporteur submits the proposal to the SG plenary for consideration. Should the Study Group agree to start the work, it assigns an Editor. The Editor then maintains the baseline text of the new work item, together with the help of liaison activities, with other study groups, as well as other SDOs. Once a text is considered mature, it is sent to the Study Group or the working group for consideration. If the Study Group or the working group is satisfied with the text, it initiates the approval process. The approval process is carried forth, the draft

recommendation is published, and any revisions, amendments, and deletion will happen with the help of members setting a new cycle in motion.

2.3 ITU Template for Gatekeeper partner use

The following template is provided to ease partner contributions to the project's standardization actions. Contributions can be of an informative nature detailing key outcomes of the project. In this context, all partners are kindly invited to provide any relevant information by filling the following form and submitting it to MI, which will liaise with the relevant ITU Question on their behalf.

2.3.1 Empty template

INTERNATIONAL TELECOMMUNICATION UNION

TELECOMMUNICATION STANDARDIZATION SECTOR

STUDY PERIOD 2017-2020

SG20-Cn

STUDY GROUP 20

Original: English

Question(s):	Q nos separated by commas (e.g 3/13, 5/16) or N/A (TSAG)	Place, dd-dd mmm yyyy

CONTRIBUTION

Source:	Insert source(s)	
Title:	H2020-857223 – GATEKEEPER	
Purpose:	[Purpose]	
Contact:	Insert contact name Insert organization Insert country	Tel: +xx Fax: +xx E-mail: a@b.com
Contact:	Insert contact name Insert organization Insert country	Tel: +xx Fax: +xx E-mail: a@b.com
Keywords:	Insert keywords separated by semicolon (;)	
Abstract:	Insert an abstract under 200 words that describes the content of the contribution in a form suitable for inclusion in the meeting report as a summary of the content of the document, including a clear description of any proposals it may contain. See also Rec.A.2, clause I.1.2 for guidance.	

[[Your text starts here.

Before submitting this document:

- Update the **information highlighted in yellow** above: document number (*n*), Question(s), source, title, and contact information.
- If you need **more contact information** rows, please insert by **copy-and-pasting** an existing one (to preserve the associated WinWord fields).
- Make sure that "**Track Changes**" is turned **off**.
- **Remove** any remaining yellow highlighting.

]]

2.3.2 Example contribution

The following document was prepared by Mandat International to be submitted to the ITU-T as an informative contribution. This example can be used to further facilitate partner's understanding of contributions.

INTERNATIONAL TELECOMMUNICATION UNION
TELECOMMUNICATION STANDARDIZATION SECTOR
STUDY PERIOD 2017-2020

SG20-Cn
STUDY GROUP 20
Original: English

Question(s): All/20 — Place, dd-dd mmm yyyy

CONTRIBUTION

Source:	Mandat International (Switzerland)	
Title:	Proposal to organise a session on eHealth at the IoT Week 2022 conference	
Purpose:	Discussion	
Contact:	Sébastien Ziegler Mandat International Switzerland	Tel: +41 79 750 53 83 E-mail: sziegler@mandint.org
Contact:	Adrian Quesada Rodriguez Mandat International Switzerland	E-mail: aquesada@mandint.org
Contact:	Renáta Radócz Mandat International Switzerland	E-mail: rradocz@mandint.org

Keywords: eHealth; standardisation; conference

Abstract: This contribution proposes the organisation of a session on "eHealth standards something" at the IoT Week 2022 conference.

This session will explore the role of IoT and Artificial Intelligence standards in the eHealth domain.

The eHealth standardisation landscape is growing with many ongoing standardisation activities led by diverse standard development organisations. While this diversity of approaches is a source of richness and innovations, fostering collaboration and convergence among numerous initiatives could contribute to the further adoption of globally interoperable standards and technologies.

Mandat International would like to invite ITU (through its ITU-T SG20 and JCA on IoT and SC&C) to organise a session on "NAME" at the IoT Week 2022 conference, in Dublin, Ireland. The session will provide a platform to:

- Foster collaboration and convergence among eHealth related Standard Development Organisations to support globally interoperable standards for the eHealth domain;
- Identify and discuss gaps and priorities for standardisation in the eHealth and Artificial Intelligence of Health domains;
- Identify ways to enhance the contribution and support of the research community for eHealth related standardisation.

The session aims at identifying new possible topics for future standardisation in ITU-T Study Group 20.

Mandat International proposes to organise this session together with ITU and in collaboration with research projects on eHealth, such as GATEKEEPER, and to invite contributions from interested SDOs and ITU Membership.

Figure 7 ITU example contribution

3 World Wide Web Consortium (W3C)

This section introduces W3C and describes different ways to contribute to the development of Web standards.

3.1 About W3C

W3C is an international member funded organisation for standards and guidelines relating to the World Wide Web, including Web browsers, the Web of Data, and the Web of Things. W3C was founded in 1994 as a hosting agreement between MIT (USA), INRIA (France) and Keio University (Japan), with Tim Berners-Lee, the inventor of the Web, as its head. In 2003, ERCIM (the European Research Consortium in Informatics and Mathematics) took over the role of the European host from INRIA. The fourth host, Beihang University (China), joined in 2013. W3C is a de facto standards organisation, and develops standards which it refers to as W3C Recommendations.

W3C endorses the OpenStand principles for standards: address broad market needs, embody diverse perspectives, leverage proprietary knowledge, serve as building blocks for innovation, drive interoperability and scalability, streamline development and implementation, reduce costs, open new markets and applications, encourage market competition, and drive global innovation and advancement.

3.2 W3C Standards

W3C is perhaps best known for its standards for Web browsers and the hypertext markup language (HTML) in particular. The Open Web Platform's strength relies on many more technologies that W3C and its partners are working on, including CSS, SVG, WOFF, the Semantic Web stack, XML, and a variety of APIs.

W3C's horizontal standards relate to the Web as a platform, e.g.

- HTML5
- CSS3
- Web APIs
- Web of Things
- Decentralised Identifiers
- Internationalisation
- Web Accessibility
- Security and Privacy

W3C's other standards relate to industry verticals, e.g.

- TV
- Publishing
- Connected Cars
- Smart Homes
- Smart Cities
- Retail

W3C's Recommendation Track covers the progress of specifications within Working Groups.

- Editor's Drafts: documents under intense discussion and revision.
- Working Drafts: Snapshots of work in progress for wider review.
- Candidate Recommendations: More mature than a Working Draft, and intended to solicit aid from the developer community on how implementable a standard is.
- Proposed Recommendations: A stable version of a standard that is submitted for review by W3C's Advisory Council for final approval as a W3C Recommendation.
- W3C Recommendations: This is the most mature stage of development. At this point, the standard has undergone extensive review and testing, under both theoretical and practical conditions. The standard is now endorsed by the W3C, indicating its readiness for deployment to the public, and encouraging more widespread support among implementors and authors.
- A recommendation may be updated or extended by separately-published, non-technical errata or editor drafts until sufficient substantial edits accumulate for producing a new edition or level of the recommendation. Additionally, the W3C publishes various kinds of informative notes which are to be used as references.
- Unlike the ISOC and other international standards bodies, the W3C does not have a certification program. The W3C has decided, for now, that it is not suitable to start such a program, owing to the risk of creating more drawbacks for the community than benefits.

W3C has several different kinds of groups:

- Working Groups – the only kind of group that can progress specifications along the W3C Recommendation Track.
- Interest Groups – have a broader role to gather use cases and requirements, preparing the way to introducing new work items in Working Groups.
- Community Groups – are open to anyone to join, free of charge. Likewise, anyone can launch a new Community Group if they can get support from a further five people.
- Business Groups – are focused on specific business sectors.

W3C's Advisory Board (AB) guides work on the W3C Process, whilst the W3C's Technical Architecture Group (TAG) provides guidance on technical issues relating to the architectural principles of the Web. W3C's Process includes royalty free commitments for any IPR needed to implement W3C Recommendations.

3.3 Contributing to standardisation

When it comes to contributing to standards work at W3C, there are a wide range of options.

Anyone can launch a W3C Community Group (CG) with the support of 4 other people. This is free of charge and can result in Community Group reports. Many CGs make use of GitHub for collaboration on documents and other resources.

Organisations can join W3C to participate in Interest Groups and Working Groups etc. where the membership fee depends on the organisation's size. There is also a process for Invited Experts where appropriate and justifiable under the process rules.

W3C welcomes external contributions, but these are subject to our patent policy if they are used as part of our standards track process and end up as part of W3C Recommendations.

W3C Interest Groups (IG) and Working Groups (WG) may invite presentations by external parties, e.g., to share use cases and requirements, and implementation and deployment experience. A further option is to organise workshops to discuss whether it is timely and appropriate to proceed to standardisation.

W3C is also open to liaisons with industry alliances and SDOs provided that W3C Members are willing to drive the dialogue, examples include IETF, OGC and OPC Foundation.

For Gatekeeper which partners plan to make contributions to industry alliances and SDOs, and what form will these take? It is unrealistic to expect people involved in Horizon projects to directly drive the development of standards given the large time commitments involved and the likelihood of work taking longer than the project's lifetime.

However, as pointed out above, there are other ways for project partners to provide effective contributions. In particular, there are opportunities for GATEKEEPER partners to present relevant work to the W3C Web of Things IG/WG. Here we are looking to the partners who have worked on the GATEKEEPER platform, and partners who have applied the Web of Things in GATEKEEPER pilots, including the open call programme.

4 HL7 International

The following section introduces the role and working methods of HL7 International (HL7)[10] and provides a detailed overview on how to submit contributions to this Standard Development Organization.

4.1 About HL7 International

Founded in 1987, Health Level Seven International (HL7) is a not-for-profit, ANSI-accredited standards developing organization dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery and evaluation of health services. HL7 is supported by more than 1,600 members from over 50 countries, including 500+ corporate members representing healthcare providers, government stakeholders, payers, pharmaceutical companies, vendors/suppliers, and consulting firms. HL7 aims to provide standards that empower global health data interoperability.

4.1.1 HL7 standards

HL7 is responsible for a large set of standards covering different knowledge domains and aspects of the health and social data life cycle. They vary from implementable specifications to Service or System Functional Models, from languages representing and sharing medical knowledge to Implementation independent Models. HL7 standards include base/primary standards (as HL7 FHIR or HL7 CDA) or derived products as functional profiles or Implementation guides.

A complete list of the HL7 standards is available in the HL7 site https://www.hl7.org/implement/standards/index.cfm
and https://www.hl7.org/implement/standards/product_matrix.cfm.

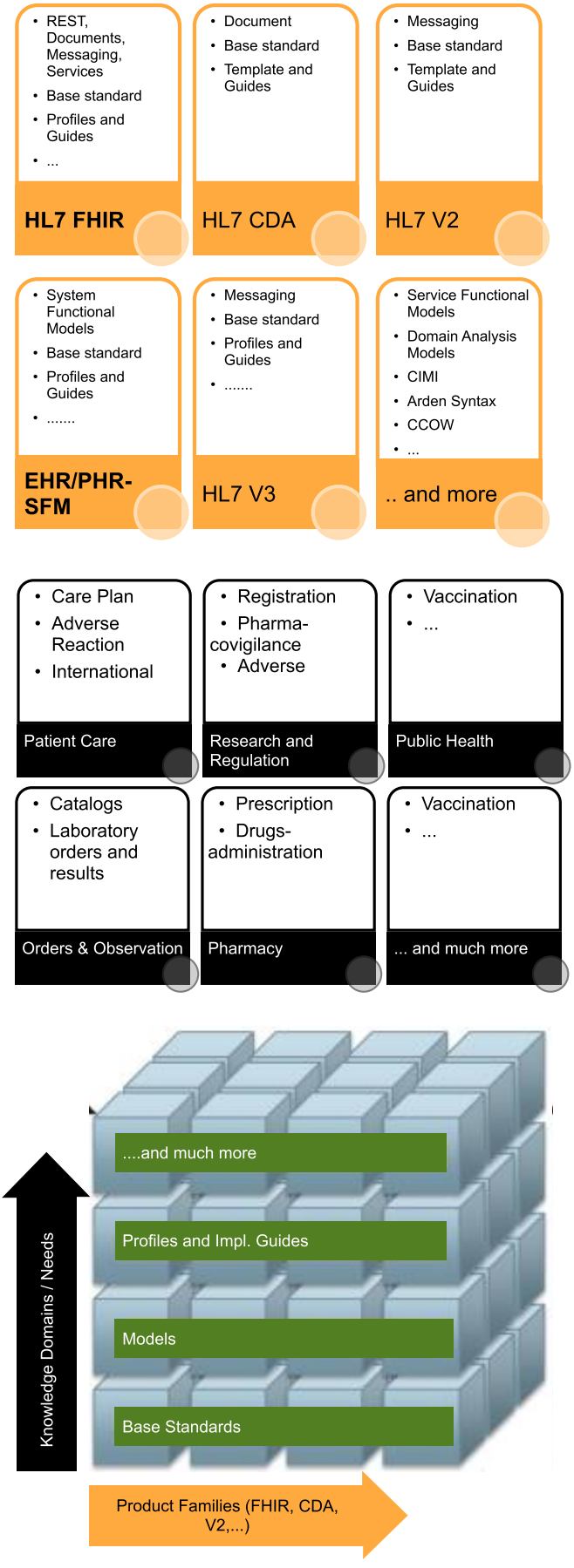
• REST, Documents, Messaging, Services
• Base standard
• Profiles and Guides
• ...
HL7 FHIR
• Document
• Base standard
• Template and Guides
HL7 CDA
• Messaging
• Base standard
• Template and Guides
HL7 V2
• System Functional Models
• Base standard
• Profiles and Guides
• .....
EHR/PHR-SFM
• Messaging
• Base standard
• Profiles and Guides
• .....
HL7 V3
• Service Functional Models
• Domain Analysis Models
• CIMI
• Arden Syntax
• CCOW
• ...
.. and more
• Care Plan
• Adverse Reaction
• International
Patient Care
• Registration
• Pharma-covigilance
• Adverse
Research and Regulation
• Vaccination
• ...
Public Health
• Catalogs
• Laboratory orders and results
Orders & Observation
• Prescription
• Drugs-administration
Pharmacy
• Vaccination
• ...
... and much more
....and much more
Profiles and Impl. Guides
Models
Base Standards
Knowledge Domains / Needs
Product Families (FHIR, CDA, V2,...)

Figure 8 HL7 products and domains

4.1.2 Organization

The HL7 International organization is divided up into 40 or so "work groups" covering different areas of healthcare, such as pharmacy, public health, research, etc.

Work groups are the bodies within HL7 that take on responsibility for developing and maintaining standards. They are where the "work" of HL7 gets done.

All work groups are open to participation by anyone with an interest in their content.

The WGs report to the Technical Steering Committee (TSC) which oversees standards development across the organization. In addition to this, there are several other management and governance bodies that manage some of the major product families HL7 develops standards for, that provide specific organizational process support, etc. These generally also report to the TSC.

Finally, HL7's Board of Directors provides strategic oversight and manages the strategic direction and financial stability of the organization.

HL7 Organizational Chart

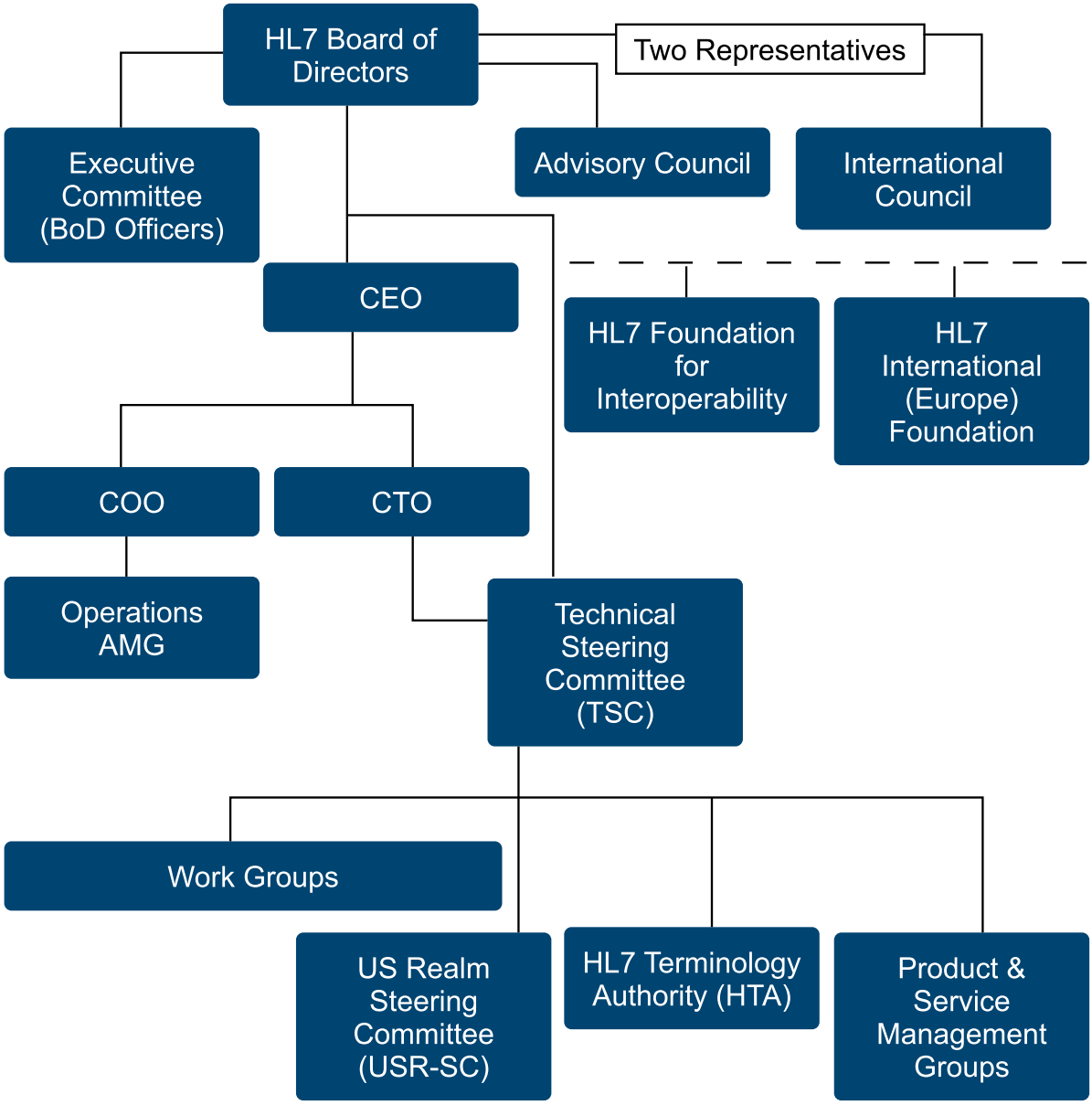

Figure 9 HL7 organizational chart

To better support the local adoption of the HL7 standards a set of regional (e.g. HL7 Europe) and National organizations (called HL7 affiliate e.g. HL7 France, HL7 Argentina) are also established.

Implementers can refer also to these organizations to contribute to the HL7 standards,

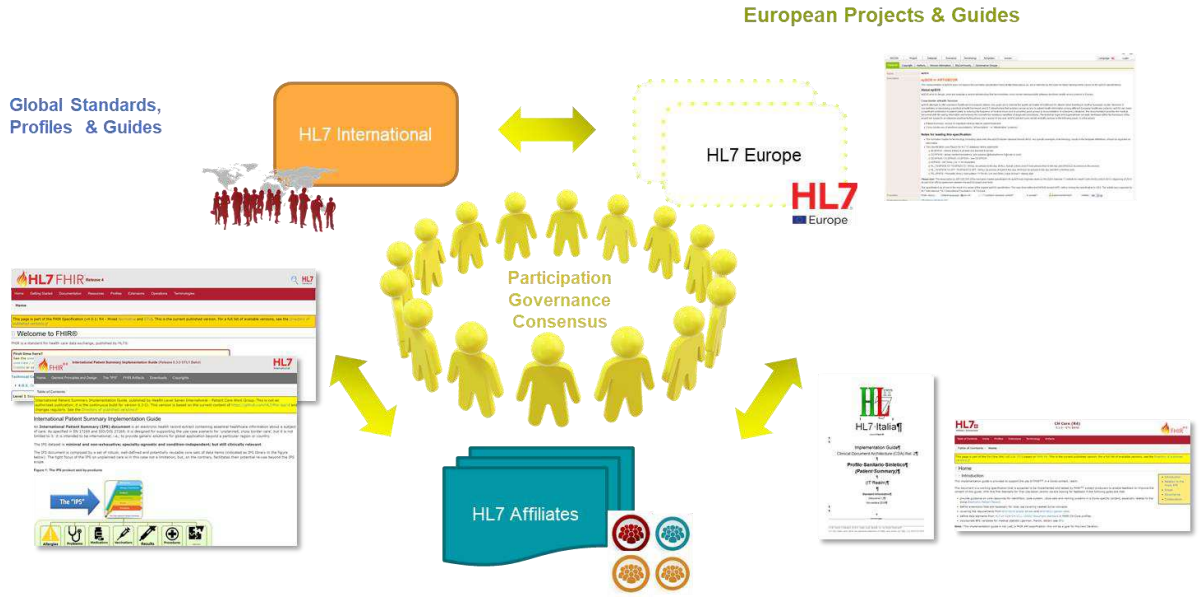

Figure 10 HL7 a cooperative network of international and local organizations

4.1.3 Getting involved

HL7 welcomes and encourages newcomers to join in discussion and contribute to the development of their specifications. HL7 encourages all participants to be members because it helps to support the organization and provides a number of benefits including reduced costs for meetings and education. Membership either in HL7 itself or one of its affiliates is a requirement in order to take on an official leadership role - i.e. be elected as a WG co-chair, be a member of one of the governance bodies. Membership is also necessary to be able to participate in the formal voting on proposed standards for free.

Non-members who are members of certain other standards organizations may be entitled to reciprocal voting rights, but otherwise non-members must pay a fee for each specification they wish to vote on.

However, beyond getting involved in governance or formal voting, contribution to HL7 standards development is open to anyone. Non-members are free to join calls, participate in http://chat.fhir.org (HL7's community discussion forum), submit requests for change to HL7 specifications and vote on decisions in work group meetings.

To engage with a particular work group, go to the work group's page on the HL7 website (http://www.hl7.org/special/committees) and either sign up to their list serve or look for the next conference call time-slot. You can also email the co-chairs and ask for the best mechanism to engage.

4.2 The journey of a Contribution

The scope of the contributions can vary from proposing a specific change to a published standard up to propose a complete new standard. The following table summarizes for some of these scopes what are the activities you may or you need to perform.

Scope / Activity	Propose a new standard / new version	Contribute to a standard development	Comment a published standard.[1]	See §
Informal community discussion	Suggested	Suggested	Suggested	Informal community discussion (listserv; chat)
Start a new project	Required	N/A	N/A	Project life cycle (PSS)
Join project/WG meetings	Part of the project life cycle	Required	Recommended	Join project/WG meetings
Commenting	Ballot comments are part of the project life cycle.	Optional	Required	Specification Feedback life cycles (Jira)

4.2.1 Informal community discussion (listserv; chat)

Informal discussions are a very important mean used by the HL7 community/ies to share ideas, experiences, thoughts, and issues; build consensus about a proposal; and so on…

There are different means that are used to accomplished this:

- meet community members virtually or in person during the HL7 WGM meetings or FHIR Connectathon events
- participating in the HL7's community discussion forum as http://chat.fhir.org
- joining one of the HL7 mailing lists (https://www.hl7.org/myhl7/managelistservs.cfm)
- Commenting / contributing through the HL7 projects confluence pages (https://confluence.hl7.org/)

HL7 communities are open to member and non-members.

[1] depending on the kind of update foreseen this case can turn into the "Propose a new standard" case

4.2.2 Join project/WG meetings

Project / WG meeting is the place where topics are discussed, and decisions are taken.

To join a meeting of a particular work group, go to the work group's page on the HL7 website (http://www.hl7.org/special/committees) and either sign up to their list serve or look for the next conference call time-slot.

Each working group has also a confluence space where you can find projects information, and the meeting agendas and minutes. The list of confluence spaces is available in the Welcome to the Confluence Pages of Health Level 7 (HL7) International page (https://confluence.hl7.org/).

4.2.3 Project life cycle (PSS)

Any standard developed by HL7 is the product of an HL7 Project. The full process from the initiation of an HL7 Project process through its' lifecycle is described by the following figure.

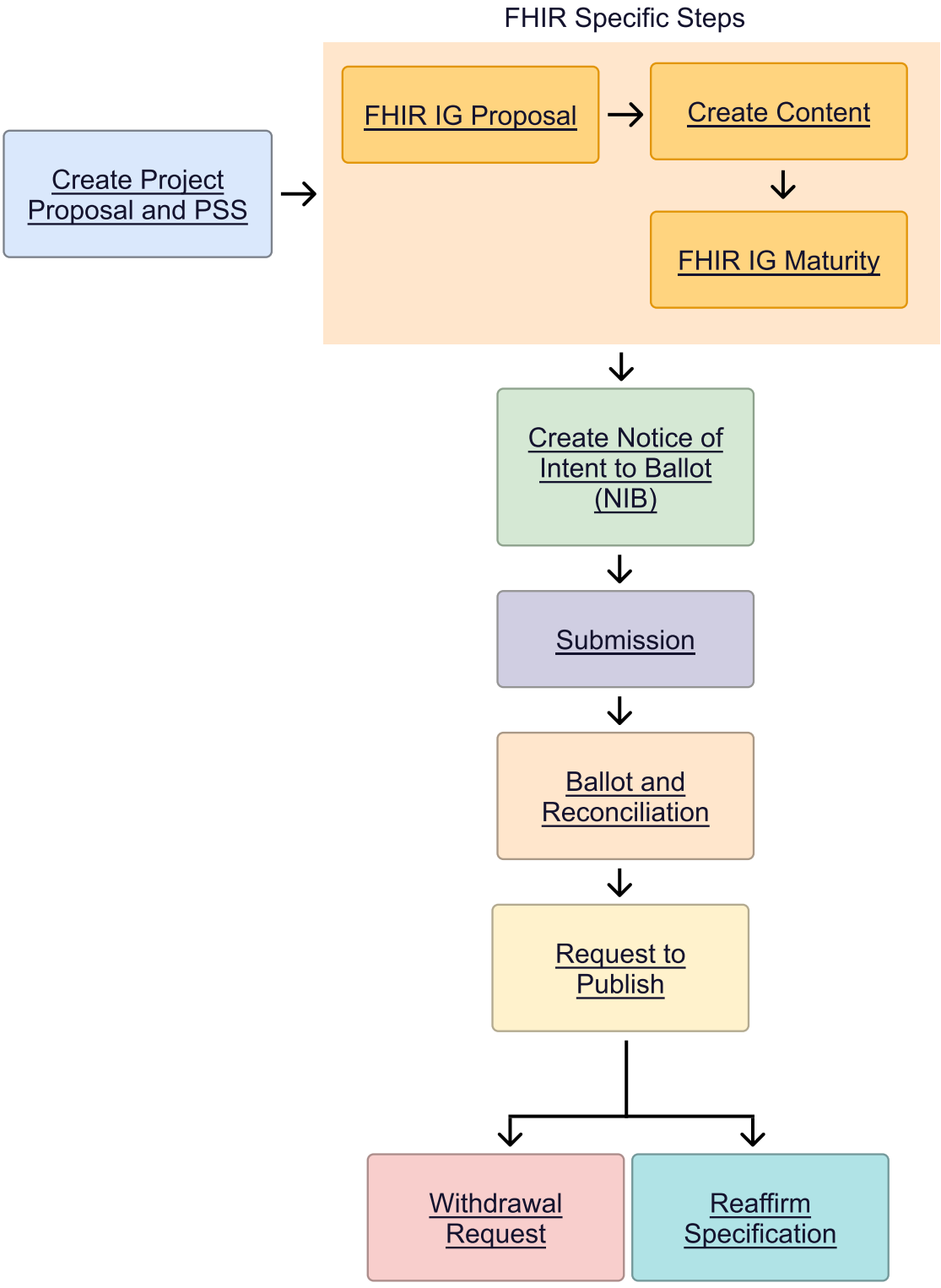

Figure 11 HL7 projects life-cycle

In this process we can recognize these main steps:

1. The Creation of a project proposal and then of a Project scope statement

2. The balloting process: when the standard is ready for review a community ballot is performed, and comments discussed and reconciled.
3. The publication of the standard
4. The re-affirmation or the withdrawn of a standard

In the following sub-paragraph some information about the initiation phase is given, more details about the entire life cycle can be found in the https://confluence.hl7.org/pages/viewpage.action?pageId=111117149 page.

4.2.3.1 Project Proposal and Project Scope Statement

Any new project in HL7 requires a consensus in the HL7 community and a WG taking this project in charge (called sponsoring WG).

The purpose of the Project Proposal is indeed to provide visibility into potential work at HL7 and to identify a potential sponsor for a project.

If a proposal is accepted a Project Scope Statement (PSS) is created in Jira (https://jira.hl7.org/projects/PSS), reviewed and finally approved or rejected.

If approved, the project team can start its developing work.

Details about the project proposal approval steps is given in https://confluence.hl7.org/display/HL7/How+to+Create+and+Review+a+Project+Proposal

The https://confluence.hl7.org/display/HL7/How+to+Create+a+Project+Scope+Statement+in+JIRA page provides details about the Project Scope Statement creation and approval process.

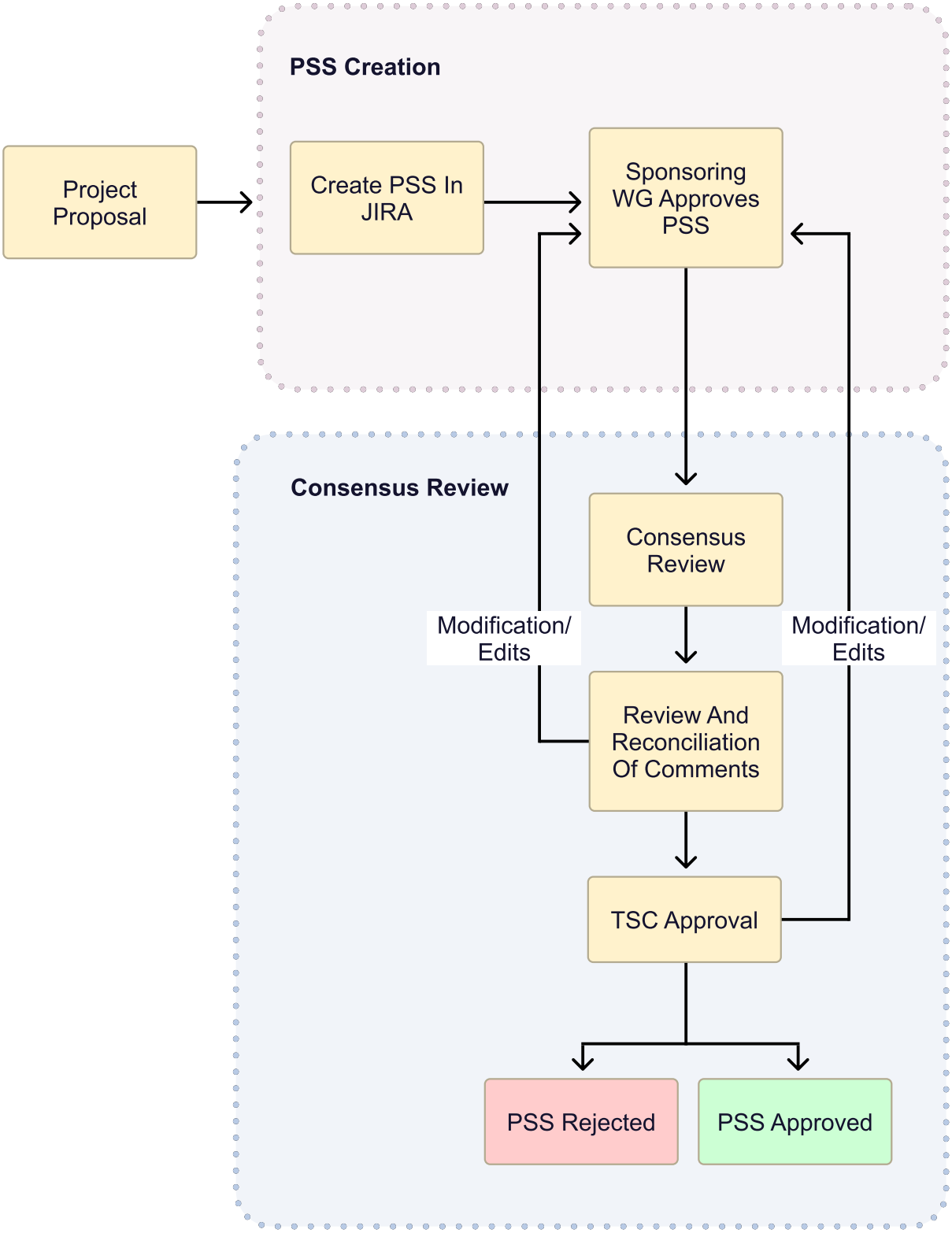

Figure 12 HL7 project proposal and project scope statement life-cycle

4.2.4 Specification Feedback life cycles (Jira)

Specification Feedback projects are the official mechanism for providing feedback about any HL7 specification. For this scope the jira tool (https://jira.hl7.org/) is used.

The process is composed by three main steps:

- Submitting new feedback
- Participating in the feedback process
- Searching and monitoring issues

In the following paragraphs some information about the how to submit new feedback is provided, more details about the entire process can be found in https://confluence.hl7.org/display/HL7/Specification+Feedback.

4.2.4.1 Submitting new feedback

An essential part of the standards development process is receiving and managing feedback from the community.

Feedback might be suggesting a feature, pointing out a place where a specification is unclear or over-restrictive, identifying a spelling or grammar issue or suggesting that an entire area needs to be rethought.

HL7 makes a special effort to solicit feedback using their ballot process, however feedback can be submitted by at any time by anyone - even if they're not an HL7 member.

In order to submit feedback, you must register as a user on HL7's Confluence and Jira systems. Individuals are encouraged to submit feedback themselves. Submitters will automatically be notified as a submitted is commented on or achieves milestones within the review process. They may also be asked questions about and/or invited to calls to discuss their feedback Therefore, it's best for feedback to be submitted directly by the individual directly impacted by or having direct knowledge of the issue being submitted.

Before submitting feedback, users are encouraged to browse through previously submitted feedback to see if the topic has already been discussed and, if so, what discussion has already taken place. It may also be helpful to search the appropriate chat forum. Duplicate requests will be closed without discussion unless they raise new points for consideration.

Feedback can be initiated by clicking on the "Create" button from http://jira.hl7.org, or in some cases, by using a link within an HL7-published specification.

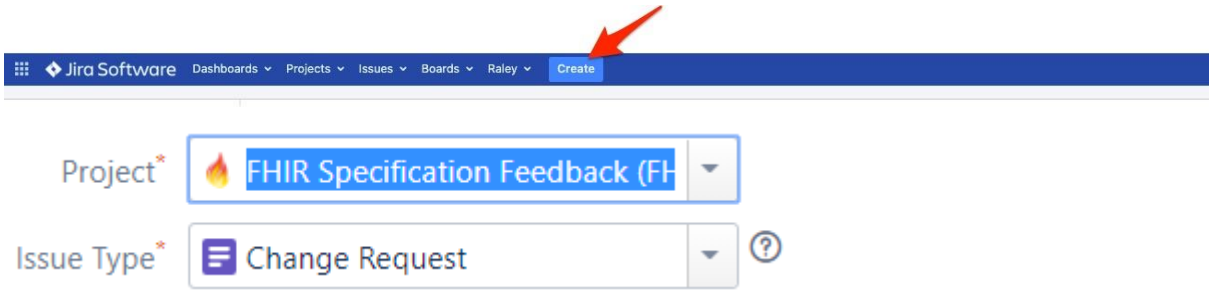

Figure 13 HL7 submitting new feedback

When submitting an issue, you will be prompted with two fields that determine the "kind" of issue being reported - and which in turn determine what fields are available to describe the issue and what the validation rules are for submitting the issue.

Submission of a new feedback item initiates a process of review by HL7 members. Submitters are supposed to follow-up their submissions, by providing additional information when needed and/or attending the meetings where their items are discussed.

4.2.5 Ballot

Balloting is the **formal process** that HL7 uses to get feedback and comments on specifications prior to publication.

With some exceptions, only members can participate to the balloting process.

HL7 specifications can be balloted at one of four levels:

For Comment ballots are used early in the development cycle to solicit feedback from the community.

Informative ballots are used to vet content that is not intended to be binding on implementers.

Standard for Trial Use (STU) ballots are used to vet content that is eventually intended to be binding on implementers. It is used to vet content that is deemed "ready to implement" by the sponsoring work group, but where there has not yet been significant implementation experience.

Normative ballots are used for final review of specifications that are intended to be binding on the implementer community and where there are strict rules around future changes to preserve a degree of forward and/or backward compatibility.

Starting in January 2022, all ballots except Reaffirmation and Withdrawal Ballots will be done using Jira Balloting. Details on this process are given in the https://confluence.hl7.org/display/HL7/Jira+Ballot+Process page.

5 ETSI

5.1 ETSI Standards & Deliverables

ETSI is a key player on the international standards scene and publishes between 2,000 and 2,500 standards every year. These include the standards that enable key global technologies such as GSM™, 3G, 4G, 5G, DECT™, smart cards and many more standards success stories.

ETSI standards are available for download in PDF format free of charge (the Word version is password protected and available to ETSI Members only): https://www.etsi.org/standards#Pre-defined%20Collections.

5.1.1 Types of Standards and Deliverables produced at ETSI

ETSI produces various types of standards and deliverables[11]:

1. **European Standards (EN)** are used when the document is intended to meet needs specific to Europe and requires transposition into national standards, or when the drafting of the document is required under a standardisation request from the European Commission (EC)/European Free Trade Association (EFTA). An EN is drafted by a Technical Committee and approved by ETSI's European National Standards Organizations.
    1.1. **Harmonised Standards** are ENs with a special status, produced in response to an EC standardisation request. They provide the technical detail necessary to achieve the 'essential requirements' of an EC Directive. They are thus key enablers of the European Single Market. ETSI produced and continue to produce numerous Harmonised Standards for the Radio Equipment (RED) Directive.
    1.2. **Community Specifications** are ENs under the Single European Sky Interoperability Regulation (i.e. in civil aviation). These ENs are also produced in response to EC standardisation requests, in co-operation with EUROCAE (the European Organization for Civil Aviation Equipment). They acquire the status of Community Specifications (CSs) when they are published in the Official Journal of the European Union.
2. **ETSI Standard (ES)** is used when the document contains technical requirements. An ES is submitted to the whole ETSI membership for approval.
3. **ETSI Guide (EG)** is used for guidance to ETSI in general on the handling of specific technical standardisation activities. It is submitted to the whole ETSI membership for approval.
4. **ETSI Technical Specification (TS)** is used when the document contains technical requirements, and it is important that it is available for use quickly. A TS is approved by the Technical Committee that drafted it.
5. **ETSI Technical Report (TR)** is used when the document contains explanatory material. A TR is approved by the Technical Committee that drafted it.
6. **ETSI Special Report (SR)** is used for various purposes, including to make information publicly available for reference. An SR is approved by the Technical Committee, ad-hoc group or the Director-General (on behalf of the GA, Board or OCG) which produced it.

7. **ETSI Group Specification (GS)** provides technical requirements or explanatory material or both. Produced and approved within ETSI Industry Specification Groups (ISGs).
8. **ETSI Group Report (GR)** is an ETSI deliverable, containing only informative elements, approved for publication by an Industry Specification Group.

5.2 ETSI standardisation process

Drawing on 30 years of experience ETSI has evolved a well proven standards-making process[12] which ensures high quality and efficiently produced standards.

All standards conform to ETSI's Intellectual Property Rights (IPR) policy, which balances the needs of standardization for public use with the rights of the owners of IPRs.Consensus & Transparency

ETSI's standards-making process is based on consensus – agreement between ETSI members – and on openness. ETSI members decide:

- What to standardize
- The timing and resourcing of the task
- The approval of the final drafts

So, the standards produced truly respond to the needs of the ICT industry.

Industry Specification Groups offer an effective alternative to industry fora. They can be set up quickly to address specific technology areas, allowing also the participation of non-ETSI members.

5.2.1 Creating a Standard

A proposal to start an item of work, such as to create a new standard or to update an existing one, must come from at least four members of ETSI and be agreed by the relevant standards group.

Technical committees or other types of working groups, made up of representatives of ETSI members and led by a 'Rapporteur', draft most of ETSI standards. ETSI members may participate in any group and work activity (other than certain security-related work where participation is controlled by the ETSI Board).

Specialist Task Forces (STFs) set up to accelerate the work where there is an urgent need. STFs are groups of technical experts who come together for a defined period to work intensively on specific items.

5.2.2 Approval of Standards

Depending on the document type, it will be approved by either:

- the members of the relevant committee approve TS, TR, SR, GS and GR deliverables.
- the entire ETSI membership approves ETSI Standards and ETSI Guides.
- In the case of European Standards, ETSI's National Standards Organizations give the approval. ENs follow the ENAP approval procedure which comprises a Public Enquiry and a weighted national Vote performed in a single process.

5.3 ETSI technical groups

To get a full view of the standardisation activity at ETSI the best is to start with the ETSI Work Programme at: https://www.etsi.org/e-brochure/Work-Programme/2021-2022/mobile/index.html.

5.3.1 Committees of special interest for GATEKEEPER

The breadth of technologies covered by ETSI standardisation committees and work programme is very large, the most relevant for GATEKEEPER are likely to be in the "Better living with ICT" cluster.

Among these technologies, we should draw your attention specifically to the work done in:

- **TC eHEALTH**
  - Scope of work of TC eHEALTH: https://www.etsi.org/committee/1396
  - 2021 Activity report: https://www.etsi.org/committee-activity/activity-report-ehealth
  - eHEALTH Technologies page: https://www.etsi.org/technologies/ehealth
- **TC Human Factors**
  - Scope of work of TC HF: https://www.etsi.org/committee/1400-hf
  - 2021 Activity report: https://www.etsi.org/committee-activity/activity-report-hf
- **TC SmartBAN** (for Smart Body Area Network):
  - Scope of work of TC SmartBAN: https://www.etsi.org/committee/1413-smartban
  - 2021 Activity report: https://www.etsi.org/committee-activity/activity-report-smartban
- **SC USER** (Special Committee User Group of ICT):
  - Scope of work of SC USER: https://www.etsi.org/committee/1417-user
  - 2021 Activity report: https://www.etsi.org/committee-activity/activity-report-user-group

The list of all ETSI committees is available here: https://www.etsi.org/committees

5.4 Becoming involved in ETSI Standardisation Work

The participation in some of ETSI technical groups (Technical Committee like TC eHEALTH, TC SmartBAN, TC HF, Special Committee like SC USER or ETSI Project) is reserved to ETSI members, whereas the participation in other technical groups (ETSI Partnership Project like 3GPP and oneM2M, Industry Specification Group, Open Source Group) is possible for both members and non-members upon signature of a specific agreement.

In addition, a non-member organisation may be invited or authorised by the Chair of a Technical Body to attend meetings, provided that their presence is justified by a legitimate interest with regard to the work currently in progress. This guest status, limited to 6-months, may be requested to help with the decision to submit a membership application.

The benefits of ETSI membership are summarised on this page: https://www.etsi.org/membership/member-benefits

ETSI Director of Membership Development, Claire d'Esclercs explains how ETSI helps SMEs grow: ETSI - Small Medium Enterprises & Micro Enterprises in standardisation https://www.etsi.org/membership/sme

5.4.1 How can research projects link to standardisation at ETSI

The ETSI New and Emerging Technologies department reaches out to research organisations and develops the links between research projects and standardisation at ETSI.

The benefit for Researchers is that they profit from interactions with ETSI's technical groups and gain early exposure and feedback from the standards community that is essential to be considered before taking the results of research to full-market deployment. Research results need to influence standards in order to have a market impact.

Industry benefits from faster exploitation of relevant research results and feedback from a far wider community. Research input is highly relevant to the early study phases of product development when multiple alternative technical solutions are evaluated. Standards need innovative contributions from researchers to advance the state of the art.

More information can be found here: https://www.etsi.org/research

5.4.2 Education about Standardisation

ETSI has developed a full training curse on standardisation for the use of organisations and academia to develop the skills and knowledge to successfully participate in standardisation work. This material is made available freely for universities and trainers to use:

ETSI - Standardization Books - Education About Standardization

The ETSI Seminar is a recurring one-day event open to all members and non-members to discover ETSI.

ETSI also provides the various modules in a Webinar format: https://www.etsi.org/events/etsi-seminar

The benefits of standardisation are generally well known, as summarized here: https://www.etsi.org/standards/why-standards

6 CEN/CENELEC

6.1 Introduction

The following is an overview of typical standardisation processes in CEN at national level, using an example from Norway. In general, Standardisation work takes place in projects. A standardisation project may be to draw up a new standard based on market needs. Other times, it is about revising an existing standard. An example of the latter is when new technology means that a standard needs to be changed.

6.2 CEN/CENELEC standardisation process

6.2.1 General

The European (and national) standardisation process is typically rooted in an idea or a suggestion to a finished standard. This work is composed of different stages. In principle, an idea or proposal can come from anyone. In general, the proposer is expected to participate in the practical standardisation work, but it is not a requirement. Limited resources shall not hinder the making of ideas and proposals for standardisation projects.

The standardisation work is organised at national, European (CEN) and international (ISO) levels. At European level, CEN[13] and CENELEC[14] work in a decentralised way. Their members – the CEN National Standardisation Bodies (NSBs) and CENELEC National Committees (NCs) of the EU and EFTA countries – operate the technical groups that draw up the standards and the CEN-CENELEC Management Centre (CCMC) in Brussels manages and coordinates this system.

A European Standard (EN) is implemented by the National Standardisation Bodies (NSBs) in 34 countries as a national standard. and is included in the standards catalogue of CEN and CENELEC's Members. The CEN and CENELEC's National Members work together to develop European Standards and other deliverables in many sectors to help build the European Internal Market of products and services, removing barriers to trade and strengthening Europe's position in the global economy.

The European Standards Bodies (CEN, CENELEC and ETSI) define a Standard as *"a document, established by consensus and approved by a recognised body that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context".*

Standards should be based on consolidated results of science, technology, and experience, and aimed at the promotion of optimum community benefits.

The development of a European Standard (EN) is governed by the principles of consensus, openness, transparency, national commitment, and technical coherence (see chapter 3). More than 200,000 experts from industry, associations, public administrations, academia, and societal organisations are involved in the CEN and CENELEC network that reaches over 600 million people.

6.2.2 Technical committees and working groups

Standardisation projects are managed by technical committees (TC). The standards are drawn up in working groups (WG). The technical committees and working groups consist of participants from, for example, companies, authorities, research, NGOs, consumers, and employee organisations.

6.2.3 Subcommittees

In some areas, the workload of the technical committees is so great that subcommittees (Sub Committee, SC) have been established. This is done to divide the workload within one technical committee, instead of splitting it into several.

6.2.4 National committees

The National Standardisation Committees (e.g., Standards Norway Committee, SN/K) draw up national standards and/or they follow the work that takes place internationally. The committees that follow international work are called mirror committees (see chapter on national standardisation).

6.2.5 Delegates and experts

Delegates and experts in a European (and global) context, come from the countries that have shown an interest in participating in the work. The participants in the TCs are national delegates, while those who participate in the WGs are experts in the field in question.

6.2.6 Openness

All affected stakeholders, such as authorities, companies, research institutions, consumers and employees can participate in the standardisation work. Financing differs between countries, some NSBs require a fee to participate, others do not. There are special support funding possibilities for small and medium enterprises in Europe, financed by the European Commission through Small Business Standards (SBS), for instance.

6.2.7 Volunteering

The standardisation work is based on voluntary participation from the parties concerned. There are rules and guidelines which all participants must follow, which function as a framework for the standardisation work.

6.2.8 Consensus

Standards shall be drawn up with the aim of reaching the greatest possible degree of agreement, but not necessarily unanimous support for the final result.

6.3 The European standardisation processes

Technically, anyone can propose work that will result in a European Standard. However, at CEN and CENELEC, the work is usually channelled by the members (the CEN National Standardisation Bodies (NSBs) and the CENELEC National Committees). In some cases, the request comes from the European Commission (previously: mandates) or from other stakeholders.

If enough CEN and/or CENELEC members are willing to be involved in the development process, the work is then assigned to a CEN and/or CENELEC Technical Committee (TC) in the field concerned. At the same time, “standstill” is enforced on all national work surrounding the same topic. This means, that if work is planned or ongoing in a national standardisation committee, it must stop the work when an overlapping standard will be developed at European level. Once the Technical Committee is established, mirror committees of stakeholders at national level decide on the national contributions regarding the development of the standard. In addition to the CEN and/or CENELEC members, Technical Committees also include several observers, such as ISO/IEC members, European Commission/EFTA, European partners including Annex III organisations, external European industry associations and other affiliate bodies.

When the proposal for a standard has been evaluated and approved, the main work on the standard or standards begins in the committees. Then the proposal goes on to the drafting stage which is based on consensus-building. When the draft standard is finalised, it goes up to public enquiry open to all interested parties. When the enquiry is over, the votes and comments on the standard are evaluated and - depending on the result - the draft standard is either published or additionally worked upon by the committee, and subsequently submitted to formal vote. Furthermore, European Standards are also developed to ease compliance with European rules and regulations such as EU legislation: Through Regulation (EU) No 1025/2012, the three European Standardisation Organisations may receive a request to produce European harmonised standards in support of EU legislation and policies.

The following is a more detailed description of the process.

6.3.1 The process in details

6.3.1.1 Initial phase

Any interested party can introduce a proposal for new work. Most standardisation work is proposed through the CEN and CENELEC Members.

Once a project to develop an EN is accepted by the relevant Technical Body, or by the Technical Board, the member countries shall put all national activity within the scope of the project on hold. This means that they do not initiate new projects, nor revise existing standards at national level. This obligation is called 'standstill' and allows efforts to be focused on the development of the EN.

6.3.1.2 Drafting a standard

The EN is developed by experts within a Technical Body. The task of the committee convenor is to bring together the different viewpoints of the members through a consensus process and reach agreements on the clauses to be set in the standard, based on agreement on the scope, terminology, and others.

The standards typically have an introduction explaining the background for making it, who has been involved and its relationship to other standards in a series, if relevant. The scope is a summary of the standard's content. Chapter 2 is an overview of other normative standards to be followed in relation to the present one. Chapter 3 is an overview of terms used in the standard, preferably the same terminology as used in other standards. Clauses start with chapter 4, and this is the normative content of the standard. Apart from the clauses there may be informative and, in some cases, normative annexes, that explain in detail technical points or other information relevant for the clauses.

Figure 14 below, is an example of a simple template for a CEN standard[15]:

1) Front page:

prEN XXXXX: XXXX

Secretariat: XXX

Introductory element — Main element — Complementary element

Einführendes Element — Haupt-Element — Ergänzendes Element

Élément introductif — Élément central — Élément complémentaire

ICS:

CCMC will prepare and attach the official title page.

2) Table of contents:

Contents Page

3) European foreword:

European foreword

This document (prEN XXXX:XXXX) has been prepared by Technical Committee CEN/TC XXX "Title", the secretariat of which is held by XXX.

This document is currently submitted to the CEN Enquiry.

This document will supersede EN XXXX:XXXX.

In comparison with the previous edition, the following technical modifications have been made:

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

[NOTE to the drafter: Add information about related documents or other parts in a series as necessary. A list of all parts in a series can be found on the CEN website.]

4) Introduction

Introduction

Text of the introduction.

Identification of patent holders, if any.

5) Scope and terminology

1 Scope

Text of the scope.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN XXXX-1:XXXX, *General title of series — Part X: Title of part*

EN XXXXX (all parts), *General title of the series*

[NOTE to the drafter: The Normative references clause is compulsory. If there are no normative references, add the following text below the clause title: "There are no normative references in this document."]

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply / the terms and definitions given in… and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

[NOTE to the drafter: The Terms and definitions clause is compulsory. If there are no terms and definitions, add the following text: "No terms and definitions are listed in this document."]

3.1
term
text of the definition

3.2
term
text of the definition

Note 1 to entry:

Fokus

6) Clauses and subclauses

4 Clause title, e.g. Subclauses

4.1 Subclause title

Text of subclause.

prEN XXXX:XXXX (E)

4.2 Subclause title

4.2.1 Subclause title

4.2.1.1 Subclause title

4.2.1.1.1 Subclause title

4.2.1.1.1.1 Subclause title

Text of subclause.

5 Clause title, e.g. Paragraphs and Lists

5.1 Text of paragraph.

7) Annex template

Annex A
(informative)

Title of Annex A, e.g. Example of a table, a figure and a formula

A.1 Clause title

A.1.1 Subclause title

A.1.1.1.1 Subclause title

A.1.1.1.2 Subclause title

A.1.1.1.2.1 Subclause title

Text of the annex.

A.2 Example of a table

Table A.1 — Table title

Table header[a]			
Table text	Text[b]		
NOTE Table note.			
[a] Table footnote. [b] Second table footnote.			

[NOTE to the drafter: For indented text, it is recommended to create new cells instead of using tabs.]

Figure 14 Template for a CEN standard with some of the chapters (Source: CEN)

6.3.1.3 Enquiry stage

Once the draft of an EN is prepared, it is released for public comment and vote, a process known as the 'Enquiry'. During this stage, everyone who has an interest (for instance manufacturers, public authorities, consumers, etc.) may comment on the draft. These views are gathered by the members who then submit a national position by means of a weighted vote and which is subsequently analysed by the Technical Body. If the results of the Enquiry show a 100% approval for the EN then the European Standard will be published.

If the results of the Enquiry show that the draft EN requires technical reworking and the results of the Enquiry do not reach a 100% approval rate, then the Technical Body updates the draft and resubmits it for another weighted vote, called the Formal Vote.

6.3.1.4 Publishing the standard

Following the approval of the EN, either from the Enquiry or the Formal Vote, the EN is then published. A published European Standard must be given the status of national standard in all member countries, who also have the obligation to withdraw any national standards that conflict with it. This guarantees that a manufacturer has easier access to the market of all the member countries when applying European Standards and this also applies whether the manufacturer is based in a member's territory or not.

6.3.1.5 Reviews of the standard

To ensure that a European Standard is still current, it is reviewed within five years of its publication. This review results in the confirmation, modification, revision, or withdrawal of the EN.

European Standards are made available in 3 official languages: English, French, and German. Members of CEN and CENELEC can translate standards into their own languages.

7 National standardization processes

An example of the national standardisation process is taken from Norway. The process is the same as in European standardisation and, in addition, there are rules for the process:

7.1 Standards Norway's role and responsibilities as a national standardisation body (NSB)

Standards Norway is the Norwegian NSB, a neutral and independent member organisation for standardisation.

EU Regulation (EU) No. 1025/2012 on European Standardisation[16] has been made applicable in Norwegian law through the EEA Consultation Act. This Regulation regulates cooperation between the European standardisation organisations, national standardisation organisations, the EEA States (Norway, Iceland, and Liechtenstein) and the European Commission. Standards Norway is assigned the task of developing Norwegian standards (NS) through this Regulation.

In the Regulation, European standards are regarded as tools that facilitate trade and promote the competitiveness of business and industry in the European Internal Market. There are consequently strict requirements for the standardisation organisations to ensure that the standards being developed do not create trade barriers.

Standards Norway is a member of CEN and is committed to implement all European standards and establishing them as Norwegian Standard. Standards Norway is furthermore obliged to comply with a set of criteria that impose requirements on the organisation's transparency, independence and consensus, efficiency and market relevance, coherence in the standardisation system, economic stability, and adequate technical solutions.

As a result of regulatory requirements, Standards Norway publishes up-to-date information on:

- all national standardisation projects,
- all standards that are/have been consulted and standards established.

Standards Norway is also a member of the ISO (the global standardisation organisation). Selected ISO standards are determined as Norwegian Standards based on a comprehensive assessment on, among other things, societal and market needs.

Standards Norway also participates in Nordic cooperation on standardisation. If at least three Nordic countries determine that there is a need to develop a common standard, guidelines have been developed for the preparation of so-called INSTA standards. INSTA standards are developed according to the same principles as other standards.

7.2 The national standardisation processes

Standards are developed in open processes. Stakeholders who report their interest in participation and then become members of a standardisation committee can influence the work through the development process. Other stakeholders may comment on proposed standards in open hearings.

The standardisation work takes place in standardisation committees established by Standards Norway. The members of a standardisation committee are obliged to follow the rules described in a specific code of conduct.

As a result of the Regulation on Standardisation, Standards Norway must notify CEN on the start-up of all national standardisation projects. This will contribute to transparency about the national work programme for standards and will prevent possible duplication of work and avoid trade barriers.

7.3 Main principles of the national work

All standardisation work is based on the principles of:

- Openness
- Volunteering
- Consensus

These principles are also enshrined in CEN's and ISO's regulations.

> *The definition of consensus is in accordance with EN 45020:2006 Standardisation and related activities — General terms:*
>
> *"General agreement characterized by the fact that no significant affected party persistently disagrees on significant points obtained through a process where it has been tried to take into account all parties concerned and reconcile any conflicting arguments. NOTE: Consensus does not necessarily imply unanimity."*

The principles and rules of standardisation must be followed when designing all standard documents.

7.3.1 Right to control

Standards Norway is entitled to all documents prepared by Standards Norway. Those who have contributed to the standardisation work do not have the right to copy and disseminate standards or standardisation proposals without the consent of Standards Norway. In the committee work, the committee members confer the right to control their contributions to the standardisation work of the relevant standardisation organisation (Standards Norway, CEN, and ISO).

7.4 Processing of new project proposals

Proposals for a new standard can be put forward by members, the board of directors, sector boards, various stakeholder groups, other stakeholders and by Standards Norway. Standards Norway will assess the proposal based on societal and market needs in addition to access to resources (participation and financing).

New project proposals from ISO and CEN are submitted to relevant stakeholders or standardisation committees for assessment of needs and interest. The feedback from the stakeholders forms the basis for Standards Norway's possible follow-up, recruiting of experts, establishment of mirror committees and other initiatives.

7.5 Types of standard documents

Standards Norway prepares several types of documents. These are:

- Norwegian Standard (NS)
- Technical Specification (SN/TS)

- Norwegian Specification (SN-NSPEK)
- Technical Report (SN-TR)
- Different types of forms and tutorials

7.6 Contents of the Standard Documents

The standard documents are developed based on the needs of society and the market and are formulated in accordance with the current writing rules. The current writing rules are established in "ISO/IEC Directives, Part 2 — Principles and rules for the structure and drafting of ISO and IEC documents" including national supplements and Norwegian national additions.

When designing the content, several of considerations should be considered. These are:

- sustainability aspects (environment, climate, circular economy, etc.),
- universal design (UU) requirements,
- consumer aspects,
- adaptation for small and medium-sized businesses,
- gender aspects,
- suitability for conformity assessment.

7.7 The national process

The process for the preparation of international standards is described in ISO directives and the CEN's Internal Regulation. The process to be used to prepare national standard documents is based on the guidelines from CEN and ISO.

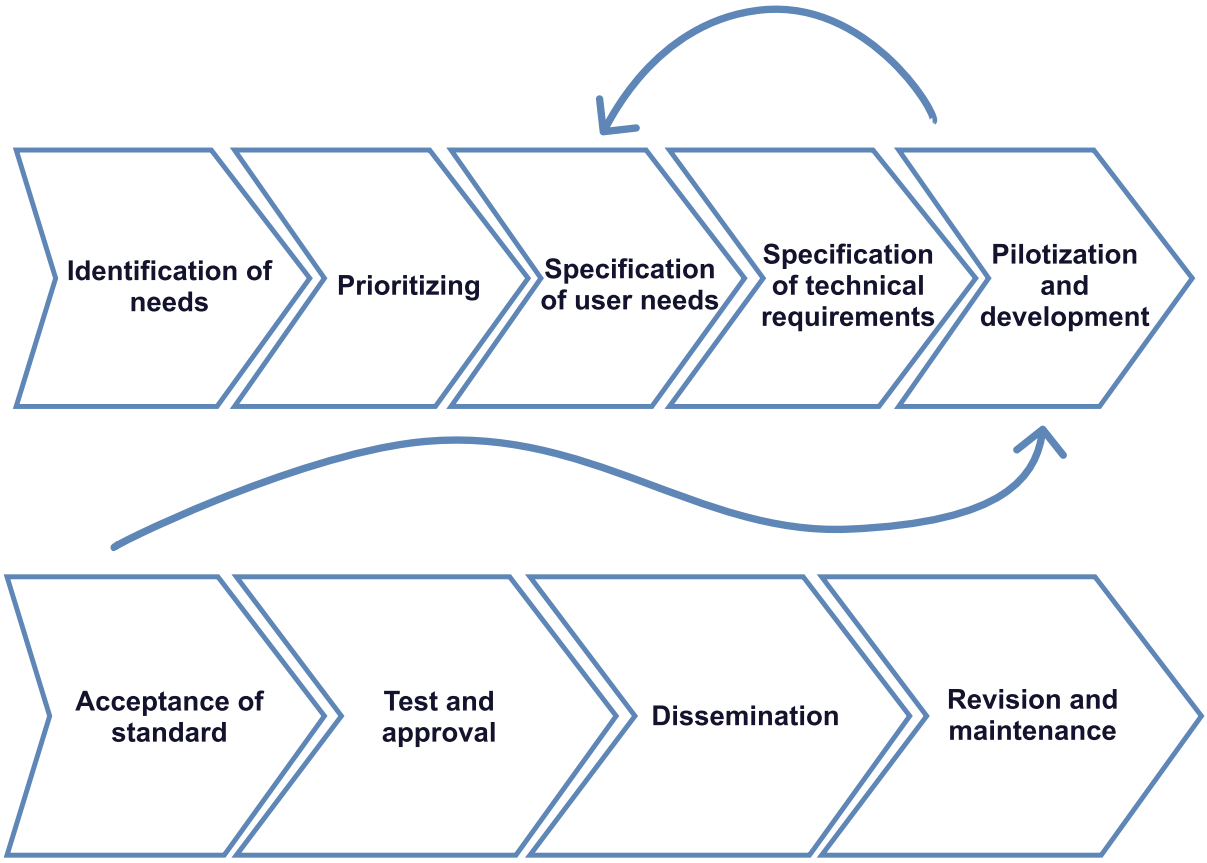

Figure 15 Illustration of the standardisation process (Source: Standards Norway)

When drawing up national standards, the following conditions should be considered:

7.7.1 Standstill

This is a commitment Standards Norway[17] has as a member of CEN and it entails a halt to all national standardisation work which conflicts with existing European standards or ongoing European standardisation work. In such cases, Standards Norway shall stop the work or revise the scope of the national standardisation project.

7.7.2 Consultation

For all proposed standards, an open consultation of at least eight weeks is carried out. The consultation proposals shall be freely available to everyone during the consultation period through Standards Norway's consultation portal. If some stakeholder groups have been underrepresented in the standardisation committee, specific measures shall be considered to include them during the consultation period.

A proposal can be submitted for consultation even if there is no full agreement in the committee on its contents. In such a case, the consultation document shall state on which points there is disagreement.

All comments received are processed by the committee and the processing must be documented.

Stakeholders from other countries shall be given access to national consultation proposals if requested. Comments from these are handled by the committee in the same way as national comments.

7.7.3 Note

For other types of standard documents, separate guidelines apply for consultation.

7.7.4 Adoption

All standardisation documents are adopted by Standards Norway.

Where sector boards have been established, the sector board shall receive the proposal for a national standard for their information before the adoption of Standards Norway. For the sector board for Petroleum, special rules apply, ref. Directive A001 Rules for the professional work and rules for structuring, writing and approval of NORSOK standards.

7.8 Work in national standardisation committees

7.8.1 Types of committees

A committee can either:

- have a mandate to prepare or revise nationally prepared standardisation documents, or
- be a mirror committee for one or more committees in CEN or ISO.
- Committees can have both tasks.

7.8.2 Establishment and closure of a standardisation committee

Standardisation committees are created as needed from the group of interested stakeholders. The establishment of a standardisation committee must be approved formally by the CEO of Standards Norway, or the person to which this has been delegated.

The Standardisation Committee is initially appointed for a period of three years. The committee can be reappointed for new periods of three years. In this context, the composition of the committee shall be assessed.

The closure of committees is decided by the CEO.

7.8.3 Mandate

A mandate shall form the basis for all standardisation work. Where sectorial boards (for instance the Sector Board for Health) cover the subject area for standardisation work, the Board mandates the work.

7.8.4 Appointment of committee members and committee participants

A standardisation committee shall be balanced with members from relevant stakeholder categories. The Norwegian categories are:

- Code Category Description (example)
- Industry: Manufacturers, designers, service providers, retailers, banking, and financial institutions, industry, and trade organisations
- A1: Small and medium-sized businesses: Businesses with less than 250 employees
- B Authorities: Local, regional, and national governmental bodies
- C Consumers: Consumer Organisations
- C1: Social Groups Associations representing the elderly, people with disabilities

- D: Worker organisations, Professional associations
- E: Academia Universities, educational institutions, research institutions
- Testing, certification, and accreditation: Testing laboratories, certification, and accreditation businesses
- G: NGOs Non- profit organisations that safeguard social conditions
- G1 Environment GOs: Non-profit organisations that focus on environmental issues

The CEO or the person to whom this has been delegated approves the proposed committee members and committee participants in the standardisation committees.

The standardisation committee shall be balanced and have sufficient participation. In this context, balance in the composition should also be considered regarding age and gender. If balance between different stakeholder categories is not maintained during the work of the committee, new members and/or participants shall be requested.

A committee member is a company, organisation or government agency that has been formally appointed. The committee participants are the committee member's representatives in the committee.

To ensure transparency regarding national standardisation work, observers from other countries may be appointed to a standardisation committee when the committee prepares national standards and in special cases. Observers do not have the right to vote in the committee and are therefore not included in the decision for whether consensus has been reached.

It is not a requirement that the committee member represented by the committee participant is a member of Standards Norway.

Committee participants shall actively follow the work throughout the appointment period. A committee participant who has not participated in committee meetings or provided input to the committee work in one year can be excluded from the committee.

7.8.5 Creation of working groups

A standardisation committee can establish subordinated working groups. The working group's mandate may be to investigate specific issues. After finishing the work, the working group will be closed. The working group reports to the standardisation committee, which approves the results of the WG's work. The working group's participants shall also be participants in the committee and appointed by it.

7.8.6 Election of committee chair

The chair (convenor) of the committee shall be elected by the committee. The chair shall act neutrally during the work. The project manager may, in consultation with the CEO, propose a candidate for the convenor position and if this is not successful, the CEO can engage an external candidate for the convenor position.

7.8.7 Election of chair (convenor) of working group

The chair of working groups is elected by the standardisation committee.

7.8.8 Project Manager

The project manager for the work is appointed by Standards Norway and shall take care of the project management, technical considerations and ensure professional compliance with other standards.

7.8.9 The duties of the Standardisation Committee

Preparing national standard documents.

The Committee shall:

a) follow up and submit the produced documents in accordance with the committee's mandate.

b) prepare proposals for one or several Norwegian Standard(s) or revise an existing Norwegian Standard. The work may also include the preparation of other standardisation documents and additional products.

c) clarify whether the committee members contribute content that includes patents or other copyrighted material. Such content shall be processed in accordance with applicable patent guidelines.

d) decide to submit a proposal for consultation. This can be done even if there is no full agreement on the content. In the case of a consultation paper, it shall be stated which points there is disagreement about.

e) prepare a commenting document showing how the committee has dealt with incoming comments. A new consultation shall be carried out if the consultation comments lead to significant changes in the proposed standard.

f) consider the possible translation of a Norwegian Standard and other Norwegian standardisation documents and guidelines to other languages.

g) assess whether the proposal can be adopted as a Norwegian Standard.

h) assess and document whether standards are still relevant (at least every 5 years) and whether they should be revised.

7.8.10 Follow-up of international standardisation work

The Committee shall:

a) follow up and submit standardisation document(s) in accordance with the committee's mandate.

b) safeguard Norwegian interests in the standardisation work in CEN and ISO through monitoring, participation in and follow-up of the international work.

c) follow the rules, routines and guidelines described in ISOs and CEN's regulations.

d) contribute to the consensus on the standards set by CEN and ISO when this does not conflict with Norwegian interests.

e) prepare Norwegian comments on proposed standards at the various stages. Promote a-nonconformities comment if the proposed content of the European standards does not comply with Norwegian laws and regulations.

f) submit a recommendation to Standards Norway's voting on the international standard proposals. In the event of consensus in the mirror committee, Standards Norway will vote according to the recommendation. If the recommendation is in violation of CEN and ISO regulations, Standards Norway can vote against this recommendation.

g) propose a Norwegian title for international standards to be adopted as a Norwegian Standard and assess the need for a national preface or amendment, propose delegates to meetings of international committees and Norwegian experts in international Working Groups.

h) Participants in technical committees or subcommittees are appointed as Standards Norway's delegates in the work and shall represent the Norwegian view during the standardisation work.

i) Participants in Working Groups are appointed as independent experts.

j) consider auditing or withdrawing the existing Norwegian Standards if ISO standards with similar content are established by ISO.

k) assess whether the proposed new European Standard conflicts with the existing Norwegian Standard. As a consequence of this, withdraw or modify the content in the Norwegian Standard that conflicts with the European standard.

l) assess the need for translation of standards or proposed standards into Norwegian language and contribute to obtaining funding for this work.

m) propose any implementation of ISO standards such as a Norwegian Standard (NS-ISO).

n) propose new international projects if there is Norwegian interest and funding.

7.9 Treatment of a lack of consensus in the process

7.9.1 Lack of consensus in the preparation of national standards

Consensus shall be reached (i.e., the greatest possible degree of agreement, but not necessarily unanimous support for the final result) in the committee that the proposal is ready for adoption as a Norwegian Standard. In the event of a lack of consensus regarding a limited issue, the Committee may consider withdrawing the points concerning this issue. In the event of a lack of consensus on significant issues, the matter is raised with the CEO, or his or her representative, to find a solution.

The CEO may decide to use a dispute resolution for closure of the work, or the work may be put on hold. In the event of a dispute resolution, the CEO appoints one or more neutral persons to conduct the arbitration.

If, after attempts at dispute resolution, it is impossible for the committee to complete the work, the committee shall assess whether the document can be released with less formal status than as a Norwegian Standard (for instance a guideline). A final decision will be made by the CEO at the recommendation of the committee.

One or more members of the committee may appeal the decision to Standards Norway's Board of Directors.

7.9.2 Lack of consensus in national mirror committees

In the event of disagreement in the mirror committee about one or more Norwegian comments, the committee chairman, together with the project manager, will discuss the matter with the parties to try to find a solution. If this does not succeed, Standards Norway refrain from commenting on where there is a disagreement.

In the event of a disagreement about voting in the mirror committee, the committee chairman, together with the project manager, will discuss the matter to find a solution. If this does not succeed, the committee may choose to vote "abstain." The matter can also be raised with the CEO for a decision.

A decision can be appealed by one or more members of the committee to Standards Norway's Board of Directors.

7.10 Complaints

Standards Norway shall ensure that it is possible for everyone to complain about standardisation processes, standards, and the content of the standards. All complaints to Standards Norway shall be registered as deviations in Standards Norway's Quality System and be dealt with by Standards Norway. If relevant, the response from Standards Norway shall provide an account of any possibility of appeal and procedure for this.

7.11 CEN/ISO secretariat responsibility

Where Standards Norway has assumed responsibility for an international secretariat, the rules, routines, and guidelines described in ISOs and CEN's regulations must be followed.

7.12 Develop and approve NORSOK standards

NORSOK standards are drawn up by the Norwegian petroleum industry to ensure value-added and cost-effective processes and services on the Norwegian shelf and that the safety aspect is safeguarded.

Standards Norway has entered into an agreement with the owners of NORSOK on the development, operation, maintenance, and sale of the NORSOK standards. A procedure has been prepared for this work enshrined in Directive A-001 Rules for the professional work and rules for structuring, writing and approval of NORSOK standards.

In accordance with international agreements, Standards Norway is obliged to publish all new standardisation projects, standards for consultation and new standards. This includes national, European, and global standardisation work.

8 AIOTI

AIOTI is a public-private cooperative activity between industry, research institutions and the European Commission. It was set up to support coordination and exploitation across Horizon 2020 IoT projects, and to provide guidance to the European Commission on matters relating to the Internet of Things, including regulatory policies and research priorities.

AIOTI has a number of working groups, the largest of which focuses on standardisation, and has several sub-groups focusing on different topics, e.g., on high-level architecture, edge computing, 5G networks, and semantic interoperability. Organisations participating in IoT related European projects are encouraged to become AIOTI members. This involves an annual subscription fee. Work is carried out through teleconferences and workshops.

W3C/ERCIM staff have contributed to AIOTI work on high-level architecture, edge computing, and semantic interoperability.

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