



Co-funded by the Horizon 2020
Framework Programme of the European Union



Deliverable D38: Standardization activities

Abstract: REACH has the ambition to influence and gain from standardization on national, European, and international level. We aim to create synergies between parallel work on these levels that will finally make a beneficial impact. Systematic parallel and synergetic work on these levels allow REACH to create a maximized impact for all involved stakeholders, and in particular, create better health and health care “ecosystems” for potential REACH end users.

This Deliverable belongs to WP9 Project management + dissemination, T 9.4 Standardization activities, T 9.8 Dissemination, and WP6 Integration, testing, evaluation, and optimization, T 6.1 Coordination of system integration activities and standards research.

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 Identifier: REACH D38
 Version (Date): 1.0 (31.01.2019)
 Due Date: 31.01.2020
 Linked WPs/Tasks: WP9/T9.4, T9.8; WP6, T6.1
 Type: Public
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Date	Activity	Status
31.03.2018	Deliverable strategy initial draft	Completed
07.12.2018	Deliverable strategy detailed draft	Completed
31.01.2019	Deliverable structure initial draft	Completed
12.02.2019	Deliverable preview for reviewer	Completed
06.11.2019	Deliverable 1 st draft	Completed
15.11.2019	Deliverable revision (Thomas Linner)	Completed
23.12.2019	Deliverable 2 nd draft	Completed
24.01.2019	Finalization	Completed
31.01.2020	Submission of Deliverable	Completed

This project has received funding from the *European Union’s Horizon 2020 research and innovation programme* under grant agreement No 690425. The content of this report does not reflect the official opinion of the European Union. Responsibility for the information and views expressed in the report lies entirely with the authors.

Tasks of the involved partners with respect to the deliverable (and respective tasks) presented in this report:

Partner	Short task description
DIN	<ul style="list-style-type: none"> • Overall lead and strategy of standardization • Facilitation of the definition of standardization needs within each TP • Contribution to ISO/TC 314 activities • Secretary of the CWA • Contribution to standardization related exchange with other EU projects • Contribution to terminology and construct standardization
TUM	<ul style="list-style-type: none"> • Contribution to ISO/TC 314 activities • Vice-Chairperson of the CWA • Contribution to standardization related exchange with other EU projects • Facilitation of the use of standards within REACH • Involvement in national (German) standardization work • Contribution to terminology and construct standardization
DTU	<ul style="list-style-type: none"> • Leading role in the context of the development of the CWA (Initiator and Chairperson of the CWA) • Contribution to terminology and construct standardization • Identification of TP4 standardization needs
TU/e	<ul style="list-style-type: none"> • Identification of TP3 standardization needs • Integration of standardization into REACH business strategy • Contribution to CWA
EPFL	<ul style="list-style-type: none"> • Contribution to facilitation of the use of standards within REACH
AM	<ul style="list-style-type: none"> • Identification of TP4 standardization needs
BZN	<ul style="list-style-type: none"> • Identification of TP3 standardization needs
Philips	<ul style="list-style-type: none"> • Identification of TP3 standardization needs • Contribution to facilitation of the use of standards within REACH
SK	<ul style="list-style-type: none"> • Identification of TP2 standardization needs • Contribution to CWA • Contribution to ISO/TC 314 activities
FIAIS	<ul style="list-style-type: none"> • Identification of TP2 standardization needs
SC	<ul style="list-style-type: none"> • Identification of TP2 standardization needs • Standards analysis in context of developing a medical evaluation plan for each TP
Arjo	<ul style="list-style-type: none"> • Identification of TP2 standardization needs
HUG	<ul style="list-style-type: none"> • Identification of TP1 and TP3 standardization needs
FIAIS	<ul style="list-style-type: none"> • Identification of TP2 standardization needs

Contents

Contents	4
Key expressions	5
List of Tables	7
List of Figures	8
1 Introduction	9
1.1 REACH overall hypotheses and goals	9
1.2 REACH toolkit and Touchpoints	9
1.3 Ecosystem approach and system verification and validation by trials	10
1.4 REACH to market: a simplified structure	11
1.4.1 Medical purposes.....	11
1.4.2 Market segmentation:.....	12
1.4.3 Technology management:.....	12
1.4.4 Business and marketing.....	13
1.5 Tasks and goals of this deliverable	13
2 Context of task and REACH overall standardization strategy	14
3 Standardization landscape	16
4 Outline and detailed description of the carried-out standardization activities	20
5 Initiation, coordination and dissemination of standardization activities	22
5.1 International (ISO): Active involvement in ISO/TC 314 Ageing Societies	22
5.2 European (CEN): Initiation of the CWA process	27
5.3 Dissemination activities	30
6 Summarization, interpretation, generalization	34
7 References	36
8 Appendix	38
8.1 List of relevant standards and literature	38
8.1.1 Facilitation of the use of standards within REACH	38
8.1.2 Ethical, social, and inclusion dimensions.....	38
8.1.3 Privacy aspects	38
8.1.4 Legal and liability aspects	39
8.1.5 Usability, accessibility and acceptability	39
8.1.6 Data formats, platforms, ICT elements	40
8.2 CWA Project plan	40
8.3 ISO/TC 314 Presentation	41

Key expressions

Abbreviations for partners:

AH: ArjoHuntleigh

AM: Alreh Medical

CU: University of Copenhagen

DTU: Technical University of Denmark

EPFL: École Polytechnique Fédérale de Lausanne

HUG: Hôpitaux Universitaires de Genève

SC: SmartCardia

SK: Schön Klinik

TU/e: Eindhoven University of Technology

TUM: Technical University of Munich

ZZ: ZuidZorg

AAL: Active and Assisted Living.

Activation: Physical and cognitive activation before an incident or way to keep patient as long as possible in a good baseline health state.

Activities of Daily Living (ADLs): Activity categories (e.g. dressing, bathing, feeding, etc.) which are necessary to maintain care independent living.

AHA: Active and Healthy Ageing.

Ambient sensors: Sensors not worn on the body but integrated into the environment, everyday objects, PI²Us, etc., primarily supply in REACH the context and labelling.

CWA: CEN Workshop Agreement.

CCMC: CEN-CENELEC Management Centre.

CEN: European Standardization Organization.

D: Deliverable report.

ETSI: European Telecommunication Standards Institute.

ICT: Information and Communication Technology.

IEC: International Electrotechnical Commission.

ISO: International Organization for Standardization.

ITU: International Telecommunication Union.

IWA: International Workshop Agreement.

M: Project month within the project duration (e.g. M19 refers to project month 19, namely August 2017).

NSB: National standardization bodies.

SAG: Strategic Advisory Group.

STAIR: STAndards, Innovation and Research.

Stakeholders: In REACH the term “stakeholders” refers to the entire network and the diversity of players, partners, shareholders, stakeholders, end users, organizations, companies, institutions, and others that relate to, act in, are impacted by, and/or are interested in the activities, developments, and goals of the project.

T: Task defined in the project proposal.

TC: Technical committee.

Touchpoints/Engine concept: structures the envisioned REACH product-service-system architecture, into manageable research and development clusters.

Touchpoints: The “Touchpoints” will act as “graspable” front ends towards the end users (elderly). The Touchpoints will serve as data gathering devices and as mediators of services and interventions coordinated by the Engine towards the end user. Each Touchpoint is modular and made up of several subsystems which allow adapting the system both for a particular person or setting, as well as over time.

Use case setting: Use case setting refers to the four solution operators, and this report refers to them as use case settings since they reflect concrete application scenarios.

Wearable sensor: Worn on the body, obtain in REACH primarily uni-/multivariate physiological signals.

WG: Working group within the technical committee.

WP: Work package defined in the project proposal.

WS: Workshop e.g. on CEN level.

List of Tables

Table 5.1 Relevant technical committees	30
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List of Figures

Figure 1-1: REACH solutions help to modify and optimize trajectories of physical capacity (image adapted from WHO “World Report on Ageing and Health”)..... 9

Figure 1-2: REACH Toolkit Wheel and its connection to the four Touchpoints..... 10

Figure 1-3: Ecosystem approach and system verification and validation by trials 11

Figure 1-4: Preliminary draft of the REACH consultancy firm website 12

Figure 3-1: Standardization landscape – National, European and international standardization structure 17

Figure 3-2: Contribution to standardization activities on the different levels 18

Figure 4-1: Main tasks within the REACH standardization strategy..... 20

Figure 5-1: ISO/TC 314 Participants..... 23

Figure 5-2: ISO/TC 314 Timeline 24

Figure 5-3: CWA development process 27

Figure 5-4: Timeline of the initiated CWA 29

Figure 6-1: REACH contribution on national, European and international Standardization landscape 34

1 Introduction

REACH creates new market opportunities for European industry, including SMEs to capitalize on European high-tech-knowhow, to make Europe a market leader in prevention technologies, meanwhile tackling the ultimate cause of rising healthcare expenditures.

1.1 REACH overall hypotheses and goals

REACH develops, matures, and integrates products, processes, and solutions that seek to prevent older citizens from loss of function and decline as a major cause of physical inactivity. As such, the REACH system transforms clinical and care environments such as homes and everyday life, day care centers and other forms of care into highly personalized and data-driven early intervention systems that engage older people in preventative and rehabilitative activity, primarily physical activity but also with regard to cognitive, mobility, social and nutritional aspects (see **Figure 1-1**).

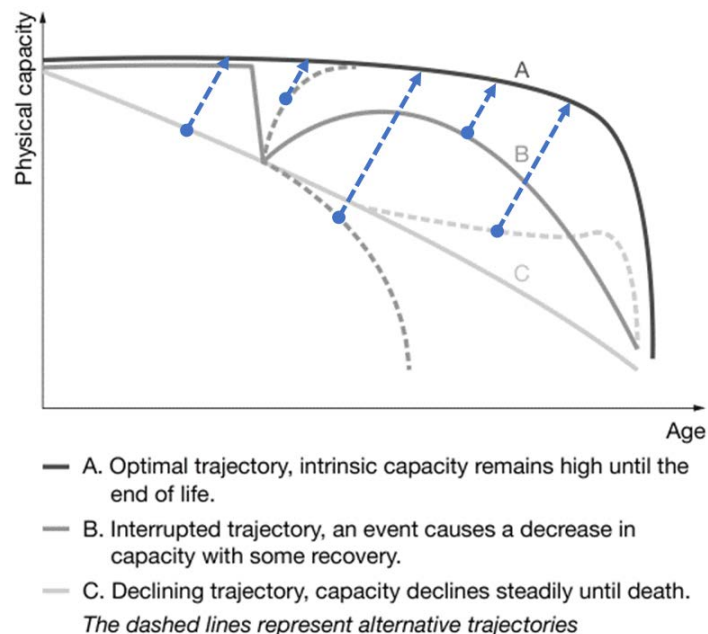


Figure 1-1: REACH solutions help to modify and optimize trajectories of physical capacity (image adapted from WHO “World Report on Ageing and Health”)

1.2 REACH toolkit and Touchpoints

The REACH toolkit guides the technical implementation of REACH. The toolkit comprises a series of partially independent components or “raw elements” developed by the partners, which can be classified into 11 categories (sensors, analytics and ML-tools, devices, smart furniture, exercise and behavior change schematics, human-machine-interfaces, data storage platforms etc.). REACH has developed and refined a design methodology (Sensing-Monitoring-Intervention/SMI workflow) for the use case specific combination and integration of these elements (see **Figure 1-2**).

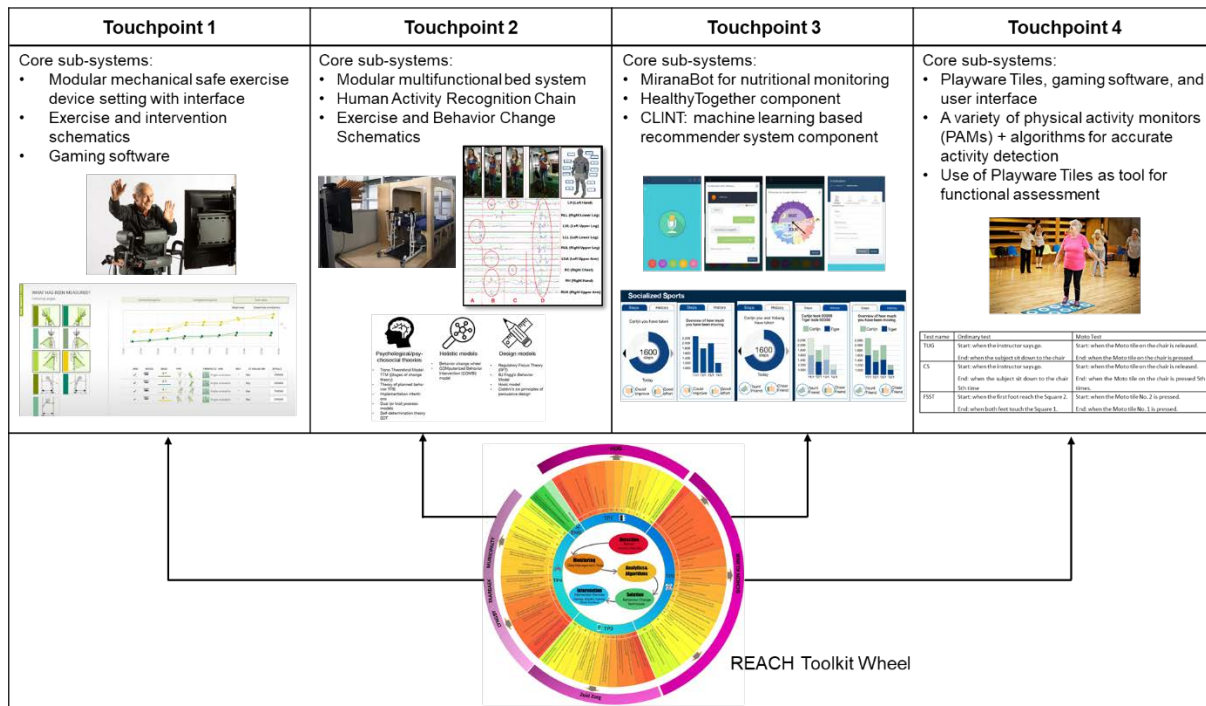


Figure 1-2: REACH Toolkit Wheel and its connection to the four Touchpoints

The REACH toolkit approach allows the tailoring of solutions that create value for end-users, care providers and health care payers alike. It does so through the combination, integration and adaptation/re-design of its elements towards the different contexts of different countries, different payment and reimbursement structures (e.g., insurance or tax-based), specific use case settings and processes and, most importantly, individual end-user needs and capabilities. (SK/Schön Klinik, HUG/Geneva Hospital, ZZ/ZuidZorg, Lyngby/Lyngby Municipality). In this context, REACH demonstrates its ability to integrate, cross-integrate, share and interchange its elements (e.g. several Touchpoints share standard elements that were, to a certain extent, adapted to the use case setting) and co-create (REACH believes that the ability to identify, incorporate and design / develop new case-specific elements for each use case setting is important to the achievement of useful and appropriate solutions.).

1.3 Ecosystem approach and system verification and validation by trials

REACH achieves its objectives through highly integrated sensing-monitoring-intervention chains representing comprehensive solutions that are exemplarily and iteratively adapted in the project to the ecosystems of a series of care settings throughout Europe (homes, hospitals, care homes, day care facilities, communities, etc.) for older individuals. REACH implements, demonstrates, tests, and validates (by more than 27 small- to medium-sized trials) through those settings, customized and personalized instances of this chain. A unique feature of REACH is the integrated utilization of personalized behavior change and engagement techniques informing about the development of the products and solutions (sensors, interfaces, devices, etc.).

REACH implements a combination of wearable and ambient sensors for each Touchpoint along with a set of co-adapted Machine Learning elements. Machine Learning is used as a core element in multiple ways, e.g. to predict Activities of Daily Living (ADLs), recognize physical activity and behavior trends, detect deviations of patterns and critical situations, cluster and profile people, and inform the effectiveness of the assignment of certain

interventions. Personalized Intelligent Interior Units (PI²Us; smart furniture devices) are used to seamlessly integrate the above described functional elements into daily life in the different target use case settings. Last but not least, REACH has developed practices and schematics to assess the implications of the use of its solutions with regard to privacy, legal, and ethical aspects in order to ensure technology acceptance by end-users, caregivers, and other care and medical professionals (see **Figure 1-3**).

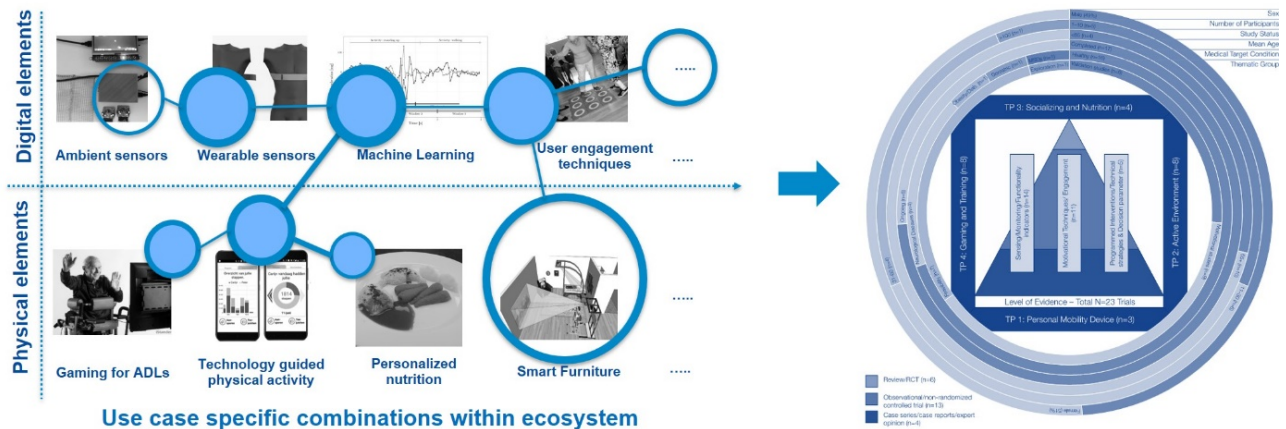


Figure 1-3: Ecosystem approach and system verification and validation by trials

1.4 REACH to market: a simplified structure

In order to work towards market implementation REACH needed to clarify and sharpen the medical purpose of its solutions, develop a regime for market segmentation, facilitate the preparation of medical certification and IPR protection activities, and define concrete business and marketing procedures.

1.4.1 Medical purposes

- **Touchpoint 1:** System: Prevent, maintain, and restore balance, muscle strength, and muscle endurance. Patients: Patients who already have mild to moderate limitations due to polyneuropathy, stroke, advanced age, incomplete cross sections, or mild cognitive impairment. Environment: Care homes, rehabilitation institutions, day care environments, offices of occupational and physical therapists, etc. Use under the supervision of instructed personnel; no 1:1 care necessary.
- **Touchpoint 2:** System: The system is intended to facilitate patient mobilization and help monitor vital signs and potentially dangerous situations. Simultaneously, it should recognize when a patient needs stronger nursing or therapeutic support and then support him or her in the partial takeover of activities. Patients: Patients with moderate to high restrictions of self-care (Activities of Daily Living) and / or with motor and / or cognitive impairment due to a neurological, medical or other disabling disease. Environment: Hospital or other nursing environments. System is able to alert a specialist, care professionals, or other skilled or semi-skilled personnel. Use in the absence of skilled or semi-skilled personnel, which only has to be available nearby.
- **Touchpoint 3:** System: App for behavior detection/monitoring, analysis, and modification. Patient: Healthy or not seriously ill people, especially in adulthood. The system can also be used under medical supervision to improve the treatment of chronic diseases (diabetes, sedentary lifestyle, obesity, etc.). Environment: Everyday environment up to assisted living. Use if necessary, on the recommendation of a doctor.

- **Touchpoint 4: System:** A training guide to improve walking movement capability, gait safety, stability, endurance, and selective leg movements. The system is also able to capture and monitor parameters of gait safety (balance), walking speed, and endurance for functional assessment purposes and to detect physical activity trends and critical situations. **Patient:** People with gait and stability limitations while still able to walk. **Environment:** For groups of older people in sports groups and in day care facilities and for self-training. Can also be used for input measurement for allocation to suitable programs and groups.

1.4.2 Market segmentation:

For business and marketing purposes, a simplified REACH structure includes and scales down the solutions developed as part of the Touchpoints in four major target market segments (see **Figure 1-4**):

- For developers of new products
- For health care institutions
- For homes
- For communities

Techniques from the field of motivational segmentation and behavior change are used to further sub-classify these segments and link them to REACH solutions.



Figure 1-4: Preliminary draft of the REACH consultancy firm website

1.4.3 Technology management:

REACH develops products that are allocated at the intersection between medical and non-medical products. REACH therefore evaluates the market potential for each solution, classifies its solutions and develops associated roadmaps and regimes for medical

certification. These activities are supported by REACH's active involvement and lead in numerous standardization frameworks on national, European (CEN), and worldwide (ISO) levels

1.4.4 *Business and marketing*

REACH is currently preparing the formation of a “REACH Active Ageing GmbH” which will serve beyond the project as an integrator of REACH partner’s individual products and services and a solution provider to above named market segments.

1.5 Tasks and goals of this deliverable

Within this deliverable the standardization strategy is explained in detail and the carried-out work is presented. This deliverable focuses on the initiation of standardization activities within REACH.

- Context of task – overall standardization strategy REACH
- Standardization landscape – overview of the different standardization levels
- Outline and detailed description of the carried-out standardization activities – overview of the carried-out tasks and their outcomes
- Initiation, coordination and dissemination of standardization activities – international level, European level, dissemination activities related to standardization
- Summary and Conclusion – summarization of all standardization activities within REACH

Major output of the standardization activities conducted within REACH includes the initiation and development of a CEN Workshop Agreement on European standardization level and the contribution to ISO/TC 314 on international standardization level.

2 Context of task and REACH overall standardization strategy

Innovative ideas can quickly fail, even if relevant experts recognize them as being progressive, when they have no access to the (global) market.

For a successful innovation, its potential needs to be appreciated by users/customers, its range needs to be increased and attention needs to be raised. In general, innovations are highly crucial as they ensure competitiveness¹ within the EU.

Standardization within research and development (R&D) projects under the EU Framework Programmes is seen as a pivotal factor in bridging the gap between the innovative outcomes of an R&D project and the (global) market: Researchers, innovators and national standardization bodies (NSBs) are brought together and with the development of new standards, customer trust, interoperability compatibility, and confidence in the innovation can be advanced.

That standards play a vital and sometimes invisible role in supporting not only economic growth but also competitiveness, innovation, and societal welfare is acknowledged¹.

A standard is a consensus-based document that provides state of the art and is developed by all interested stakeholders. The development of a standard is a well-structured, process, and it can take time to get the fully-consensus needed for the publication of a standard. Thus there are fast-track alternatives on national (DIN Specification – DIN SPEC) and European (CEN Workshop Agreement – CWA) and international (International Workshop Agreement – IWA) level that allows the creation of a technical specification that underlies a process and is drawn up under the auspices of a standardization body. These alternatives allow the initiation and development of a technical rule within the limited duration of a research project. The fast-track alternatives are not the same as a formally-developed, fully-consensus standard, but it also has the power to create a market pull for the innovation.

NSBs have a strong network of experts from various backgrounds (manufacturers, consumers, businesses, research institutes, public authorities and testing bodies, etc.) who are responsible for the standardization work in specific sectors². By interacting with these experts, the specific stakeholders' needs of an innovation can be thoroughly assessed and taken into account. Furthermore, standardization is an open process based on clear rules and transparent proceedings³. These transparent rules and the stakeholder engagement contribute to the creation of confidence in the innovation.

One example of the development of a standard for an innovative idea as a springboard to the global market is the German national DIN specification DIN SPEC 4885 – *Fibre-*

¹ Source: The annual Union work programme for European standardization for 2017. Available on: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2016:357:FIN> [01/24/2020]

² Source: <https://www.din.de/en/about-standards/din-standards> [05/11/2020]

³ More information can be found on: <https://www.din.de/en/about-standards/din-standards> [01/24/2020]

reinforced plastic composites - Shear test method using a shear frame for the determination of the in-plane shear stress/shear strain response and shear modulus⁴. This shear test method described in DIN SPEC 4885 is of high interest within the automotive industry as the test can be used for large-series production and has a low-scatter of results. The method was developed by two engineers who worked for the German Federal Institute for Materials Research and Testing (BAM) and founded their own company. The bi-lingual (German and English) DIN SPEC helped to disseminate their testing method on international level: It is used by e.g., the BMW Group in the development of fiber-reinforced plastic (FRP) structural component for electric cars. Soon, the DIN SPEC 4885 was developed into an international standard recognized by ISO and recognized by the European standardization organization (CEN) and is available as EN ISO 20337 around the world. DIN SPEC 4885 is therefore an excellent example that the specifications developed with the help of a standardization body have the power to exploit the enormous economic potential that lies in innovative ideas.

Thus, the integration of NSBs into R&D projects can be of high strategic relevance. Beyond creating a market pull, they can provide an analysis of existing standards that are important for the project. That can be a crucial success factor, as it ensures acceptance and usability also in terms of interoperability etc. Further, it can help to reach compliance with legal requirements such as EU Directives/Regulations, which is of high interest in the highly regulated field of health. Raising awareness and foster the use of existing standards can help to overcome challenges appearing when entering the global market. Standards can provide methodologies and solutions to overcome these challenges and, therefore, can also directly decrease production costs, when the product does not have to adapt to other demands at a later stage of development.

This deliverable will present and explain the standardization strategy within REACH and will focus on the archived tasks that have been undertaken and on their impact.

⁴ Available on: <https://www.beuth.de/de/technische-regel/din-spec-4885/197461551> [01/24/2020]

3 Standardization landscape

This Section introduces standardization as an important strategic tool and explains the different levels of standardization, as there is international, European, and national standardization. Furthermore, it gives an overview of the existing standardization landscape in the field of active and healthy ageing by mentioning related technical committees. This Section also introduces the technical committee ISO/TC 314, which is of high interest and connected with the REACH activities.

Standardization is a key strategic tool to agree on terminologies, methodologies, requirements, quality criteria, etc. in a specific field to make a product, process, or service fit for its purpose⁵. Thereby standardization can drive innovations e.g., as it can be agreed on product requirements including safety, health, compatibility, etc. and guidance on how to archive them can be provided.

Especially in the case of older and dependent people, it is essential that the equipment used is individually customized to the unique needs and can easily be adapted to the changing abilities of each individual. Furthermore, key aspects such as privacy, data security, and safety, interoperability, accessibility, and usability have to be considered when aiming for a sustainable and long-term implementation of new technologies into people's lives.

A standard is a document, established by a consensus of all interested stakeholders and should be based on the consolidated results of science, technology, and experience, and aimed at the promotion of the optimum community benefits. A standard is approved by a recognized body i.e., a standardization body⁵. Standardization bodies exist on a national, European, and international level.

On the international level, three official standardization bodies exist, the International Organization for Standardization (ISO), the International Electrotechnical Commission (IEC) and the International Telecommunication Union (ITU).

On the European level, an identical structure does exist. There is the European Committee on Standardization (CEN), the European Committee on Electrotechnical Standardization (CENELEC) and the European Telecommunication Standards Institute (ETSI).

On the national level, there are different structures and standardization bodies in different countries. Each country can nominate one standardization body to represent the country on the international level. European countries can additionally be represented by one standardization body on the European level.

⁵ EN 45020:2006 *Standardization and related activities - General vocabulary* (ISO/IEC Guide 2:2004)

DIN, the German Institute for Standardization, is a non-profit organization recognized as the German national standardization body representing Germany within CEN and ISO⁶ (see **Figure 3-1**).



Figure 3-1: Standardization landscape – National, European and international standardization structure ⁷

The input of interested stakeholders to standardization activities is organized in standards technical committees (TCs). A TC is responsible for a distinct area of operation and coordinates the corresponding standardization activities in a specific field. Interested stakeholders can send their experts to TCs to cover their interest in the standardization work⁸ and benefit from the network and information.

For contribution to standardization activities on the European and/or international level, the interested stakeholder needs to be a member of the national mirror committee of the TC of interest. A mirror committee is responsible for getting the national stakeholders' input and/or opinion in the specific field of the TC on international and/or European level. The national mirror committee sends out delegates and experts to the European or international TC to

⁶ Source: <https://www.din.de/en/about-standards/a-brief-introduction-to-standards>, <https://www.iso.org/member/1511.html> [10-22-2019]

⁷ Source: <https://www.din.de/en/din-and-our-partners/din-in-europe/european-standardization>. [10-23-2019]

⁸ Source: <https://www.din.de/en/getting-involved/standards-committees> [10-28-2019]

contribute to the standardization activities. Delegates represent the national opinion within the Technical Committee. Each TC has a substructure with so-called working groups (WG). In the WG, the actual standards development takes place, whereas the technical committee combines several WGs within one broader field. National TCs can send experts to these working groups (see **Figure 3-2: Contribution to standardization activities on the different levels**)

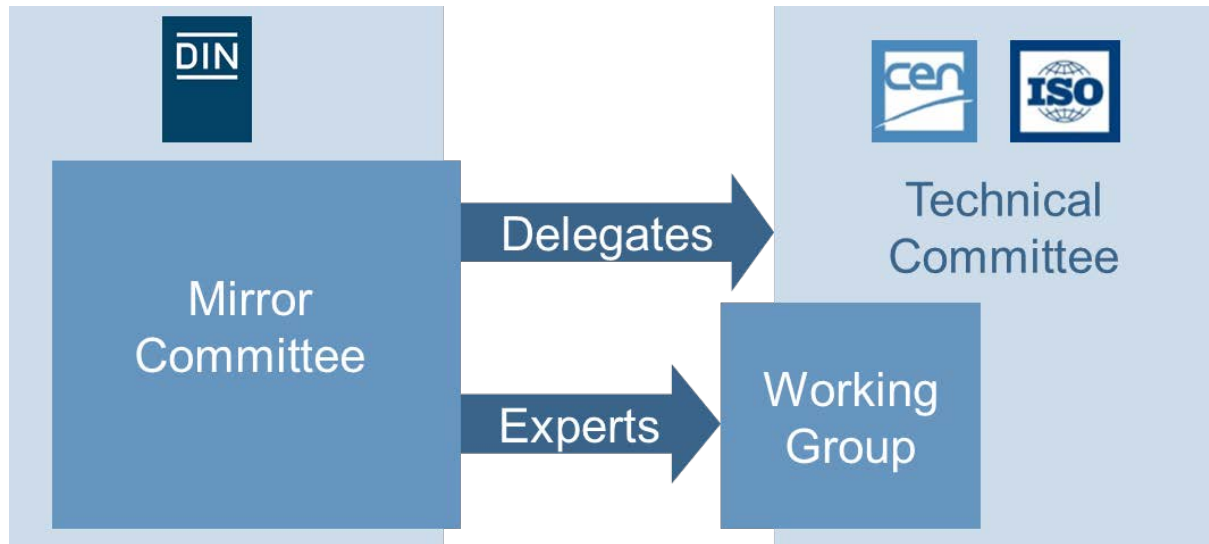


Figure 3-2: Contribution to standardization activities on the different levels

Seen from the perspective of the already existing standardization landscape, active and healthy ageing touches a variety of different and very broad fields, such as Active and Assisted Living (AAL), accessibility, health services, assistive products, design for all, etc. TCs cover these topics within the international, European, and national standardization bodies.

The following lists give an overview of the TCs on the international and European level that are relevant for REACH:

European level

- CEN Healthcare Services Focus Group
- CEN/TC 122 – Ergonomics
- CEN/TC 251 – Health informatics
- CEN/TC 293 – Assistive products for persons with disability
- CEN/TC 362 – Healthcare services - Quality management systems
- CEN/TC 431 – Service chain for Social Care Alarms
- CEN/TC 447 – Horizontal standards for the provision of services
- CEN/TC 449 – Quality of care for elderly people in ordinary or residential care facilities
- CEN/TC 450 – Patient involvement in person-centred care
- CEN/BT/WG 213 – Strategic Advisory Group on Accessibility
- CLC/TC 62 – Electrical equipment in medical practice
- CLC/TC 79 – Alarm systems
- CEN-CLC – Advisory Board for Healthcare Standards
- CEN-CLC/TC 12 – Design for All

- CEN/CLC/JTC 3 – Quality management and corresponding general aspects for medical devices
- CEN/CLC/JTC 13 – Cybersecurity and data protection
- CEN-CLC – ETSI JWG eAccessibility

International level

- ISO/TC 83 – Sports and other recreational facilities and equipment
- ISO/TC 159 – Ergonomics
- ISO/TC 173 – Assistive products
- ISO/TC 194 – Biological and clinical evaluation of medical devices
- ISO/TC 210 – Quality management and corresponding general aspects for medical devices
- ISO/TC 215 – Health informatics
- ISO/TC 304 – Healthcare administration
- ISO/TC 314 – Ageing societies
- IEC SyC AAL Active Assisted Living
- ISO/IEC JTC 1 – Joint Technical Committee for Information Technology

Among these TCs, the ISO/TC 314 is especially of interest as it was founded in 2017 to address the challenges of ageing societies⁹. REACH contributed to the work of ISO/TC 314 and gained from its extensive network. This will be on focus in Section 5.1.

National (German) level

The most relevant technical committee on the national level is the *NA 023 BR-01 SO Sonderausschuss Alternde Gesellschaften* as this committee deals with the challenges of ageing societies and is the German national mirror committee of ISO/TC 314. Several REACH consortium partners are active members of *NA 023 BR-01 SO Sonderausschuss Alternde Gesellschaften* to contribute to standardization activities, enlarge their network and to gain information useful for their work, especially in the REACH project. Furthermore, being an active member of the national mirror committee enables their active contribution on international level.

⁹ An official presentation of ISO/TC 314 can be found in Appendix 8.10.

4 Outline and detailed description of the carried-out standardization activities

This Section outlines the standardization strategy and describes its evolution by starting with the initial standardization activities (e.g., within WP6 T6.1), explaining the main steps that have been undertaken and by showing the initiated activities.

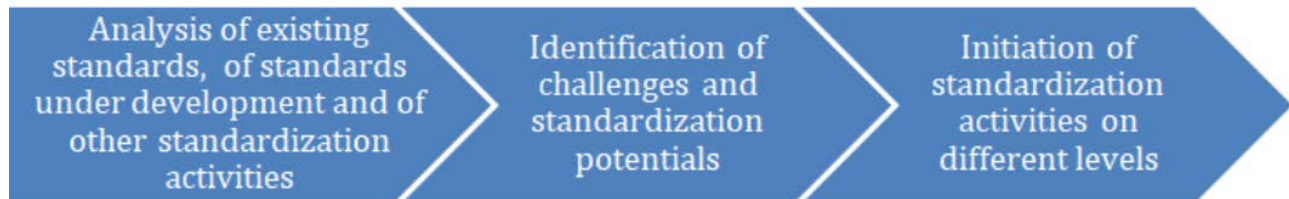


Figure 4-1: Main tasks within the REACH standardization strategy

Right from the beginning of REACH, extensive standardization activities have been pursued. In the course of the project, the focus has been broadened as to adapt to the changing development status of the REACH technologies and the needs of the project partners.

During the early development phase of REACH, the research and analysis of existing standards, of standards under development and other standardization activities on European and international level (e.g., CEN, CENELEC, ISO) was of highest priority to give inputs for the functioning, integration/cross-compatibility, and technical performance within REACH and generally facilitate the setup of an efficient system engineering process.

In cooperation with the project partners, keywords were identified, based on which a list of already existing and potentially relevant standards was generated. These standards were evaluated regarding their relevance by the particular touchpoint or engine leaders. The outcome is documented in Deliverable T6.1/D25 "Coordination and best practice guidelines for REACH system integration activities and standards research". The complete standards research is integrated as 8.8 into T1.4/D4 "PSS concepts - summary of the detailing of the product-service system architecture including aspects such as requirements, modularity, platform issues, standards, system views, interfaces, and a complementary testing approach" as the results were considered as confidential. This standards database provided a reasonable basis for partners to consider specific standards alongside the development process of their touchpoints. Furthermore, standards were utilized to set the grounding for the overarching principles of acceptability, privacy, ethics, and accessibility aspects. Deliverable 30 "User acceptance and motivation strategies" gives an overview and listing of these standards utilized in this context.

Furthermore, the outcomes of the review of existing standards and on-going standardization projects set the basis for the initiation of further standardization activities focusing on the development of standards for the REACH external environment and broader cross-compatibility and exploitation beyond the consortium and the project.

As a result of this, the strategy was pursued to get involved in standardization activities both on European (CEN) and international level (ISO).

In this context, two workshops were organized to identify challenges and standardization potentials that are relevant for REACH partners on CEN and ISO level:

- Standardization workshop 28 March 2018
- Standardization workshop 07 September 2018

The concept and results of these workshops are detailed in the Sections 5.1 and 5.2. The minutes of the workshops can be found in the Appendix 8.1 and 8.2.

5 Initiation, coordination and dissemination of standardization activities

In the early phase of REACH existing standards, standards under development and other standardization activities on European and international level (e.g., CEN, CENELEC, ISO) in the field of active and healthy ageing were researched and analyzed and set the initial basis for further standardization activities within the project. This basis enabled the further steps within the REACH standardization strategy and led to the coordination and initiation of REACH standardization activities. These activities will be in focus of this Section.

As REACH includes partners from 17 European countries, standardization activities on European level were of high interest. The European standardization is not only important for setting standards within the existing TCs. Moreover, it provides a possibility for research projects to transfer their project results in a normative document called CEN/CENELEC Workshop Agreement (CWA), which can be developed in a Workshop outside of the existing TC structure. A CWA can be used as a basis for a standard or also for certification, thus supporting the dissemination and exploitation of the project results. Furthermore, a CWA is open to every interested party, which creates a platform for interested stakeholders and allows feedback on the results outside of the project.

Within REACH, a CWA was initiated. Further information on the CWA, its development process and the content can be found in Section 5.1.

Furthermore, research projects can contribute to already existing standards to transfer results and/or contribute directly to the standard in its development phase. Depending on the field of interest, a research project can contribute to national, European, and/or international standards.

Because the ageing population has grown to a global phenomenon, ISO decided in 2017 to develop a new TC in the field of ageing societies. Being involved in the establishment of the new TC allows REACH to broaden its standardization strategy, which is a chance to transfer expertise from the project and voice European interests in the development of the ISO standard. By doing so, the REACH network was expanded beyond Europe. The contribution to ISO/TC 314 will be the focus of Section 5.1.

Furthermore, the extended personal network allowed receiving feedback to the CWA from international experts. International cooperation is highly important for enlarging the business aspects beyond Europeans borders.

Within the REACH project, standardization was seen as a creator of the channel and was therefore integrated into the business model canvases for particular TPs and REACH value propositions. This will be mentioned in Section 5.3, together with the Dissemination activities that have been undertaken regarding standardization. One of the main achievements with regards to standardization is the CEN/CENELEC Standards+ Innovation Award 2019, which was awarded to Thomas Linner for his outstanding engagement in Standardization.

5.1 International (ISO): Active involvement in ISO/TC 314 Ageing Societies

Recent developments in the international standardization landscape that will be explained in this Section allowed simultaneous activities on European (Section 5.2) and international

level. This Section will focus on the opportunity to broaden the standardization activities within REACH and increase the impact by explaining the development of ISO/TC 314 and the involvement of REACH. Further, the Section will describe the workshop that was held to contribute to ISO/TC 314 and gain information from the TC. The standardization activities will be explained. Furthermore, the transfer of research results and the broad dissemination due to the international standardization network will be presented.

ISO/TC 314

Standardization technical committees are responsible for coordinating and conduction of the standardization work in their specific field. ISO has more than 250 technical committees¹⁰, which include topics such as quality management, medical devices, spacecraft, coffee and recently also "Ageing societies".

ISO/TC 314 – Ageing societies aims at the development of standards and solutions to give guidance and tackle world-wide challenges when it comes to an ageing society. The TC was developed in 2017. The timeline of the development can be seen in **Figure 5-2**. The network of ISO/TC 314 currently contains 20 participating members and 17 observing members. **Figure 5-1** shows an overview of the members and, therefore, shows the broad network that can be reached within ISO/TC 314.

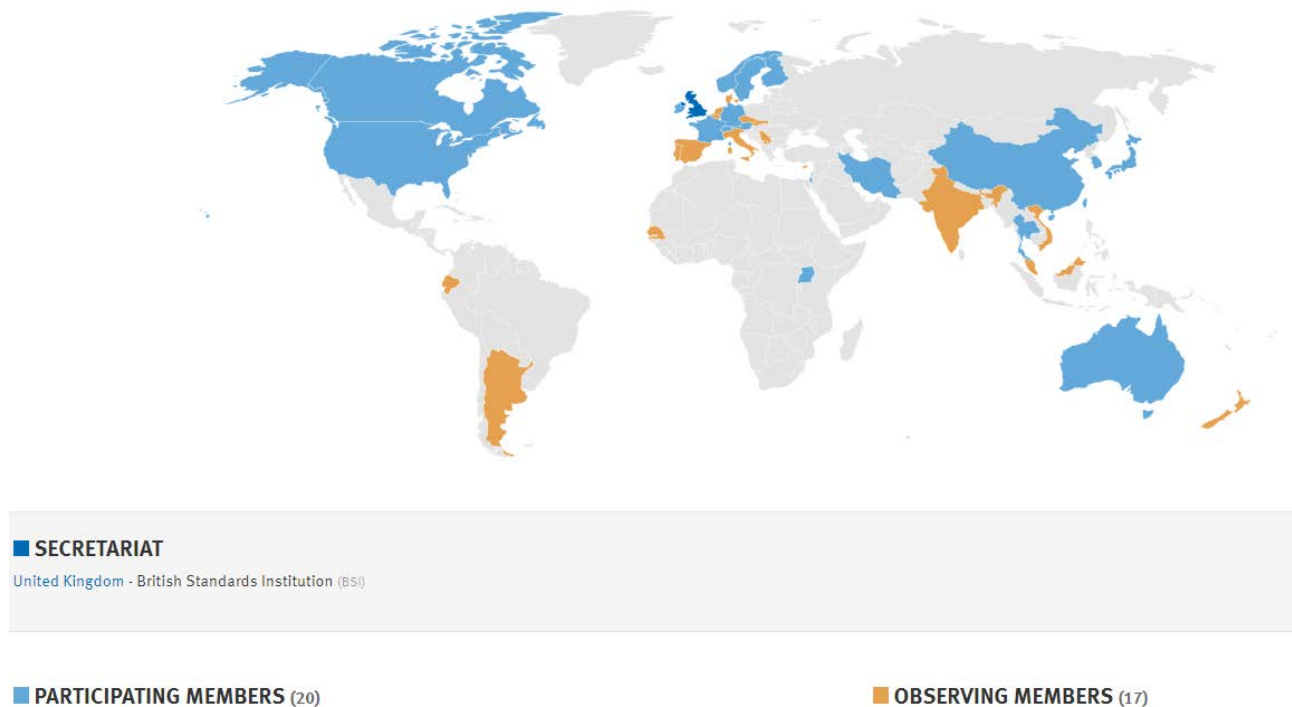


Figure 5-1: ISO/TC 314 Participants

Extensive standardization work in the field of ageing societies led to the creation of the ISO IWA 18 "*Framework for integrated community-based life-long health and care services in*

¹⁰ Source: <https://www.iso.org/who-develops-standards.html> [10-28-2019]

aged societies¹¹" which addresses challenges faced by societies that have not yet adapted to their ageing population. The further examination on where standardization can be used to overcome challenges led to the creation of the ISO Strategic Advisory Group (SAG) on Ageing Societies. An enormous breadth was identified, and the SAG was formed to set up the strategic direction and scope of future standardization work in this field. Out of this, the ISO/TC 314 was developed in 2017 with the aim to address challenges of ageing societies by developing standards.

Within ISO/TC 314, the following seven issues were listed as highly relevant:

- Community Care Services / In-home
- Technology - Enabling and Assisting
- Care Giving
- Integrated Information Management
- Future Planning
- Enabling Communities
- Building Standards

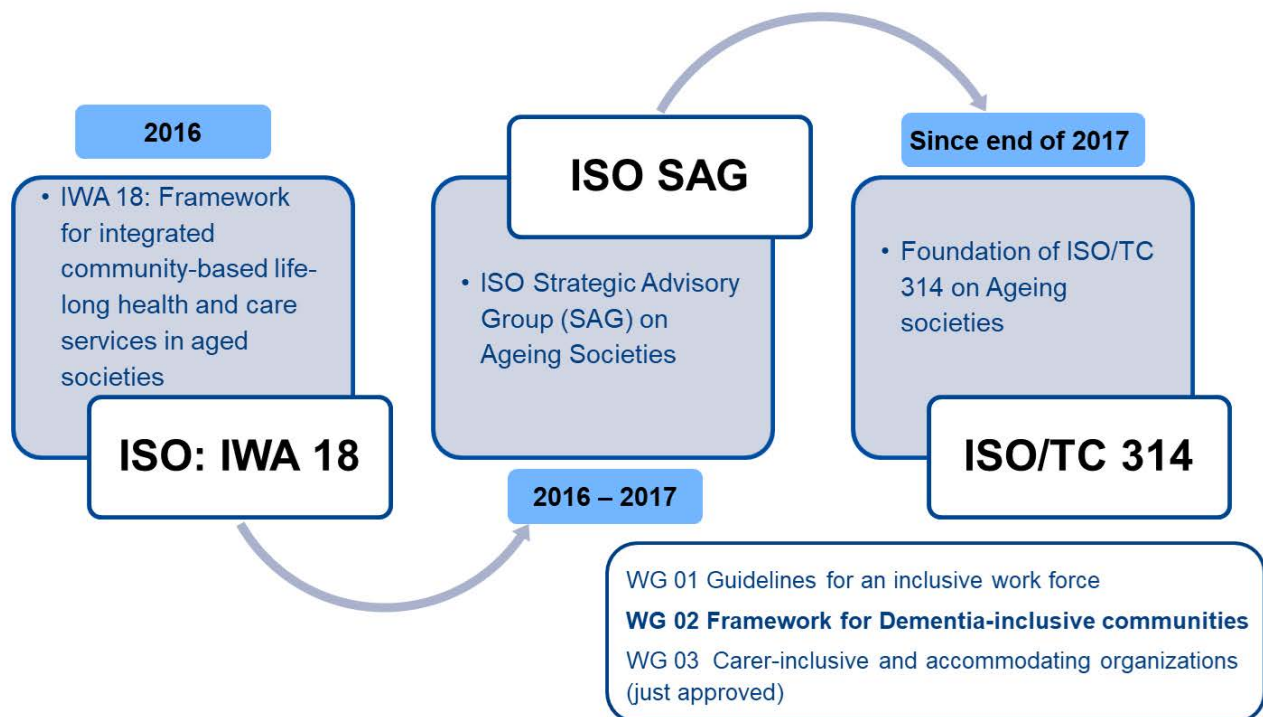


Figure 5-2: ISO/TC 314 Timeline

The outcomes of this TC will show how some key goals relating to these issues can be realized. The TCs website affirms that “standards could provide a way of setting out the

¹¹ IWA 18 can be found on: <https://www.iso.org/obp/ui/#iso:std:iso:iwa:18:ed-1:v1:en> [10-25-2019]

principles for delivering the new products, services, and solutions that will meet the future needs of our ageing societies in a new environment.”¹²

Involvement of REACH in ISO/TC 314

As this view of the importance of standardization in the field of ageing societies is shared among the REACH partners, the development of the standardization activities related to ageing societies was of high interest for the REACH partners. During the first main task of the standardization strategy, the analysis of the ongoing standardization activities, the strong thematic relation to REACH was recognized, and REACH took the initiative and got involved directly at the beginning of the TC’s formation. This offered the possibility to transfer the knowledge and experience gained within the REACH project on an international level. The standardization work of ISO/TC 314 is at present undertaken in 3 Working Groups (WGs), *WG 01 Guidelines for an inclusive work force*, *WG 02 Framework for Dementia-inclusive communities*, and *WG 03 Carer-inclusive and accommodating organizations* see **Figure 5-2**. The active engagement and the interest in the standardization activities related to ageing led to the decision of Thomas Linner to become convener and DIN to become the secretary of ISO/TC 314/WG02.

In September 2018 a workshop with REACH partners on "Standardization aspects" was held to inform all REACH partners about the recent developments in ISO/TC 314. In an interactive part, REACH partners were asked to think about topics, ideas, challenges, and solutions in their specific REACH touchpoints that could be relevant for developing the framework for a dementia-friendly community seen as a subsystem of an age-friendly community. After a presentation on the background and aim of ISO/TC 314, all present partners were divided into their REACH touchpoints for the group exercise. The results show that that one of the main points for TP 1 and 3 was the gap of standards for age-friendly environments, including construction topics such as indoor and outdoor environments, but also cultural and social aspects. Furthermore, handling of monitoring data and storage with regards to privacy and data management was rated as highly relevant. TP 2 considered several aspects as e.g., mobility, autonomy, sensor systems, and visual systems, as well as the measurements of the health status, were mentioned. TP 4 already focused on the existent standards in the field as e.g., on usability and accessibility, and focused further on the environmental issues that need to be considered.

The results fed back into the international working group and REACH core elements became part of the future standardization work. REACH was seen as an excellent example of a concept of an age-friendly environment because of the systems engineering approach and the development of personalized and modular solutions. Furthermore, the patient involvement and empowerment of older people, which is one of the elementary concepts of REACH, are also crucial for dementia-inclusiveness. REACH could deliver examples e.g., the behavior change and personalization concept that are directly based on the patient involvement. It was also agreed that patient involvement could have a positive effect on user acceptance and product rating for the provider, which is a competitive advantage compared to other providers. Predictive approaches that are digitalization/technology-based could

¹² ISO/TC 314 committee website: <https://committee.iso.org/home/tc314> [12-14-2019]

further be integrated and facilitate better inclusion if done appropriately. Another point, where REACH is a good example, is the modularity of the toolkits that can be integrated into different use cases. This has also been seen as necessary within a community. Inclusion needs to adapt to the changing needs of the individual but further even on to the changing environments. To explain the examples to the international working group Thomas Linner gave a presentation of the intervention approach in REACH and Barbara Schäpers from the Schön Klinik presented the medical dimension of dementia including the dementia life-cycle to the WG02 meeting in Hangzhou. Prof. Thomas Bock was invited as a speaker to the WG02 meeting in Berlin in June 2019, where he presented the REACH project. That shows that there is an international interest in the experiences of the REACH project.

During the work and the discussion with the experts from all over the world, new elements have identified that have fed into the development of the REACH concepts and technologies. One aspect is the awareness of common terminology. The use of an agreed terminology worldwide enables communication and can, therefore, also be seen as highly important for getting into the global market. Raising awareness on the issue led to the adoption and use of a standardized terminology e.g., regarding the correct references to older persons according to existing European and/or international definitions.

Another aspect is that new experts from the REACH consortium got involved and joined the German national mirror committee and could, therefore, directly contribute to the ISO standardization activities and exchange information with the international network of experts. In conclusion, the engagement of REACH partners in the international standardization has various advantages on both sides. REACH delivered input to the TC, as described before it served as a great example with the experiences, information, partners with different backgrounds, and also with the practical examples within their different settings as a community is considered as very broad and therefore needs to involve all kinds of environments.

Also, the REACH project has gained from this involvement: New elements were directly broad back as e.g., terminology. Furthermore, access to the network was advantageous for the project. This e.g., led to the invitation of Dr. Malcom Fisk and Dr. Atsushi Hiyama as speakers on the REACH "Conference on Active and Healthy Ageing" in Lyngby May 14-16, 2019.

It also allowed exploitation and dissemination of the project results on the international level as REACH was presented and discussed in the working group meetings and ideas exchanged with leading international experts in the field of active and healthy ageing. Furthermore, the CWA initiated by REACH partners was shared on ISO/TC level, and direct feedback was given.

Future work in standardization in the field of ageing societies and especially for communities to become more age-inclusive can create a market pull for related technologies and thereby also for the REACH devices.

5.2 European (CEN): Initiation of the CWA process

This Section focuses on the standardization activities of REACH on the European level by introducing the CEN/CENELEC Workshop Agreement (CWA) and its development process. Further, it provides a detailed description of the initiation of the CEN Workshop within REACH.

CWA - Definition

A CEN/CENELEC Workshop Agreement (CWA) is described in the CEN-CENELEC Guide 29¹³. The guide details the CWA as a document developed and agreed by participants of a CEN/CENELEC Workshop (CEN/WS). The participants of a CEN/WS do not have to be a member of a technical committee; therefore, a CWA is developed outside the typical CEN/CENELEC technical committee structure. The Workshop is open to everyone interested in participating in the development of the document. CEN publishes the CWA in at least one of the CEN official languages (English, French, German) and valid for three years with a maximum lifetime of six years. After the validation of 3 years, the Workshop participants are asked to reconfirm, revise, upgrade into a standard/technical specification, or withdraw the document.

Process

The development of a CWA follows a specific process. The process can, in general, be divided into different phases starting with the proposal phase, followed by a drafting phase in which the manuscript will be written; a development phase in which the workshop further discuss and improve the manuscript; an optional commenting phase (mandatory if the CWA deals with safety aspects) allowing the public to give comments on the script and finally the publication phase. An overview of the main steps of the process can be seen in **Figure 5-3**.

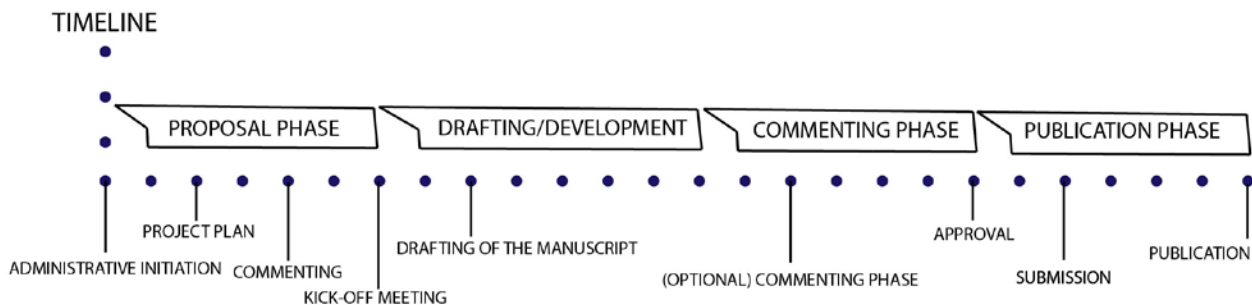


Figure 5-3: CWA development process

Process in detail

The creation of a CEN/WS starts with the proposal of a new CWA. For the formal initiation, the initiator of the proposed idea and a CEN/CENELEC (national) member or the CEN-CENELEC Management Centre (CCMC) work together on the administrative initiation of the new standardization project. The initiator provides information on the idea allowing the standardization body to check if there are existing standards or standardization activities within the topic that would permit the development of a CWA. A CWA is not allowed to

¹³ Available on: ftp://ftp.cencenelec.eu/EN/EuropeanStandardization/Guides/29_CENCLCGuide29.pdf [01-25-2020]

conflict with a standard. If there is a standardization gap that can be filled with the proposed idea, the next step can be initiated.

Then the proposers need to prepare a draft project plan, a self-assessment, and an analysis of the degree of interest amongst involved stakeholders. The documents will be made with the assistance of the committed standardization body.

The project plan specifies how the CWA will be established and includes the background to the proposed Workshop, the motivation for the creation of the Workshop, information on the market, and the legal environment, including a list of existing standards and standard related activities and documents. Also included is information regarding the Workshop proposers and Workshop participants with a short description of their backgrounds. The scope shall be included and should be very clear by also providing an overview of what is within the scope of the document and what is excluded. Furthermore, the target group of the CWA should be mentioned. The working plan and schedule should be presented, including also the work that has already been delivered. Other chapters refer, amongst others, to the Workshop structure, resource requirements, and related activities, and liaisons, usually filled in by the proposed secretary, i.e. the standardization body, of the Workshop. The project plan ends with the contact details of the proposed Chair and Vice-Chair of the CWA, the CCMC program manager, and the secretary of the proposed CEN Workshop. Aim of the project plan is to inform the public about the idea and ensure the direct participation of everyone with interest, thus the project plan is publicly available on the CEN/CENELEC website¹⁴ for a commenting period of 30 days. For the publication of the project plan, it is sent to CCMC together with a self-assessment. If the proposed topic touches a scope of a European standardization committee, the technical body shall be consulted on the CWA proposal.

With the publication, the first commenting phase starts. While the project plan is available, the public is asked to give comments. Each of the received comments should be addressed during the first physical meeting (Kick-off meeting) where the Workshop will be created.

The Kick-off meeting shall take place after the end of the first comment phase and shall be held in the country of the CEN/CENELEC national member responsible for the secretary of the proposed CWA. During the Kick-off meeting, the Workshop Chair (and Vice-Chair) is appointed, and the Workshop participants approve the project plan. By the approval of the project plan, each participant of the Kick-off meeting becomes a member of the Workshop.

After the Kick-off meeting, the drafting phase starts. During this phase, the manuscript will be drafted. The document will further be improved and discussed within the Workshop during the development phase. The Workshop can decide if a comment phase is necessary to further evolve the document and get feedback on the manuscript from the public. The comment phase lasts 60 days, where the draft will be published on the CEN/CENELEC website. The received comments will then be discussed in the Workshop.

¹⁴ Source: <https://www.cencenelec.eu/news/workshops/Pages/default.aspx> [01-25-2020]

If the Workshop decides, by approving the document, that it is final for publication, the last phase starts. The final CWA will be distributed and published on the CEN/CENELEC website¹⁵.

CWA within REACH

The identification of challenges and standardization potentials, which is the second main task within the REACH standardization strategy, is crucial for the initiation of a new CWA. Therefore, the project partners, who mainly were not yet involved in the development of a standard, need to gain knowledge about the exiting standards and standardization activities of the field to know where gaps in the standardization landscape exist. Within REACH, two REACH-internal workshops were held (in March and September 2018) to inform about standardization and to identify standardization potentials that are relevant for REACH partners and should be developed further on CEN level. REACH-based CWA topics on data platform, data schemata specifically in the context of older people were mainly identified. During telephone interviews with several project partners (FIAIS, SK, DTU, Alreh Medical), the development process was explained shortly, and the first ideas discussed. It became clear to drive forward an idea regarding the ethically responsible implementation of smart home sensing technologies for older people as filling this standardization gap would be of high interest for several REACH partners as the topic on handling monitoring data was also raised within the workshop on "Standardization aspects" in September 2018.

The proposer of the idea was Danmarks Tekniske Universitet (DTU), with the support of two other Eurotech Universities Technische Universität München (TUM), Technische Universiteit Eindhoven (Tu/e) and Schön Klinik (SK). The project plan was set up and published from the 7th of June for 30 days. The Kick-Off meeting was held in Berlin 11th of July 2019. During the Kick-off meeting, the project plan was adjusted and approved by all participants. Minutes of the Kick-off meeting can be found in Appendix 8.5. The approved project plan can be found in Appendix 8.4. Over the next six months, the CWA, with the title "*Privacy of monitoring technology — Guidelines for introducing ambient and wearable monitoring technologies balancing privacy protection against the need for oversight and care*" was developed. The timeline of the initiated CWA can be seen in **Figure 5-4**.

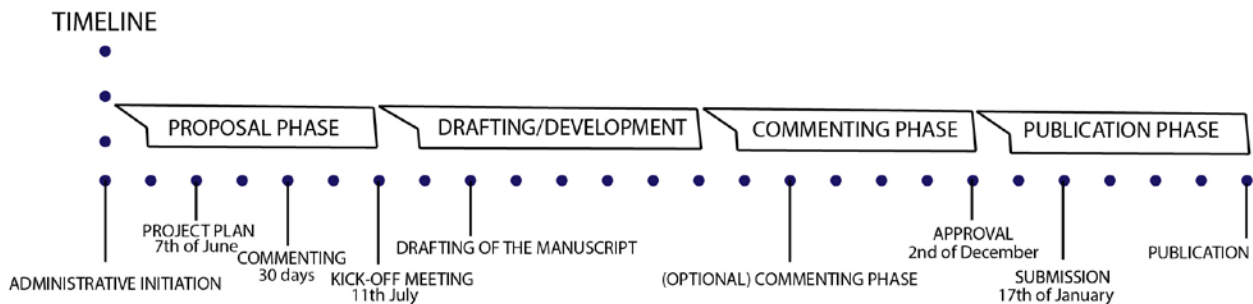


Figure 5-4: Timeline of the initiated CWA

For the drafting phase, main authors were decided to develop the first draft version of a Section. A first virtual meeting took place at August 7th to discuss the process. The Minutes

¹⁵ CWA download area available on: <https://www.cencenelec.eu/research/CWA/Pages/default.aspx> [01-09-2020]

can be found in Appendix 8.6. The drafting phase ended on September 19th. A consolidated document was shared for commenting within the Workshop. On October 1st, the document was discussed at a physical meeting in Copenhagen, and a new version was created. Minutes of the physical meeting can be found in Appendix 8.7. The main authors were asked to revise their Sections by October 14th by taking the comments gained from the physical meeting into account. The Workshop agreed, due to the limited time given for the development of the CWA within REACH, to dispense the (optional) commenting phase of 30 days. Nevertheless, the revised version was shared with the relevant technical committees for commenting (see Table 5.1) for a shorter period.

Table 5.1 Relevant technical committees

CEN/CLC/JTC 13	Cybersecurity and data protection
CEN/TC 431	Service chain for social care alarms
CEN/TC 251	Health informatics
CEN/TC 449	Quality of care for older people
ISO/TC 314	Ageing Societies
DKE IK 801	System Komitee AAL

A virtual meeting was held on November 4th to discuss the draft within the Workshop. The Minutes of the 2nd virtual meeting can be found in Appendix 8.8. Afterwards, the document was finalized and approved within the Workshop at a physical meeting on December 2nd in Munich. For more information, the Minutes can be found in Appendix 8.9. The CWA was submitted to CEN on January 17th January for publication on the CEN/CENELEC website¹⁵ as CWA 17502.

Content of the CWA

The CWA will provide guidelines for introducing, implementing, and operating sensor monitoring technologies in the private homes of citizens who are in need of care to detect critical events and trends¹⁶. It is aimed at care providers as the primary target group and on care receivers, families, developers, health authorities, and political decision-makers as a secondary target group. By using the CWA, the target groups should be guided to support an ethically responsible balance between respect for autonomy and privacy of a care receiver and the obligation to provide quality care. The document will not cover security issues and management for handling monitoring data. The document will focus on an agreement model between a care receiver and care provider, on an adaption of the consent process to achieve the balance, on risk governance, and examples of harm of duty of care or privacy.

The guidelines can be used by care providers to create confidence in their monitoring technologies. By applying the CWA, they can ensure that both the privacy and the need for care are balanced, which can increase the user's acceptance in the devices. For the REACH project, it can be used to advance the confidence to REACH solutions that will be implemented in the care receiver's homes.

5.3 Dissemination activities

¹⁶ CEN/WS 102 project plan, see Appendix 8.4

This Section focuses on dissemination activities related to standardization that have been perused within REACH. Furthermore, the integration of standardization into the business model canvases will be explained.

Collaboration with EU project PROGRESSIVE

The EU project PROGRESSIVE¹⁷ founded by the EU Commission under grant agreement number 727802 focused on ethics support of ICT related standards for active and healthy ageing intending to make a profound voice in changing mindsets.

As DIN was a consortium partner in both projects, and both projects were related to healthy ageing an information exchange was fostered between the two projects.

Thereby REACH was informed about the STAIR-AHA platform that was developed to coordinate the standardization community concerning digital goods and services that support active and healthy ageing. REACH reported and informed about the 2nd STAIR-AHA meeting on the official project website¹⁸. The exchange between the two projects was strengthened when Thomas Linner became the convener of ISO/TC 314/WG2 and Malcom Fisk, De Montfort University (United Kingdom) that coordinated the PROGRESSIVE project, the convener of the terminology group of ISO/TC 314. The exchange led to the invitation of Malcom Fisk as a presenter at the REACH conference on "Active and Healthy Ageing" in Lyngby May 14-16, 2019, where he gave a presentation on "*Ethical Imperatives around Product and Service Standards for Assistive Technologies*".

One big focus of the PROGRESSIVE project was on smart homes for older people. The conclusion of the PROGRESSIVE Deliverable D10.1 – *Draft Guidelines for Standards around ICT for AHA for Smart Homes that are Age-Friendly*¹⁹ included that standards related directly to smart homes for older people are still missing and guidance is needed. The outcome supported the decision of the REACH partners to develop a CWA on the implementation of monitoring technologies in the private homes of people that are in need of oversight and care. NEN as a partner of the PROGRESSIVE consortium indicated their interest in the topic and got a Dutch expert involved in the development process of the CWA.

Participation at the discussion event "Standardization activities within the Framework Programme Horizon Europe" in Brussels in October 2018

DIN invited the REACH project to the discussion event "Standardisation activities within the Framework Programme Horizon Europe" in Brussels, to present the impact standardization made to the project²⁰.

¹⁷ Project website: <https://progressivestandards.org/> [12/13/2019]

¹⁸ Source: <http://reach2020.eu/?p=2866> [01/25/2020]

¹⁹ Available on: <https://progressivestandards.org/wp-content/uploads/2019/01/Guidelines-for-standards-around-ICT-for-AHA-for-age-friendly-smart-homes.pdf> [12/13/2019]

²⁰ More information can be found on: <https://www.din.de/de/din-und-seine-partner/public-affairs/aktuelles/standards-helfen-forschungsergebnisse-zu-verbreiten-und-marktfaehig-zu-machen-312696> [11/08/2019]

REACH is recognized as an excellent example of how standardization can be integrated into research projects and create a valuable impact on the project. Prof. Bock presented the cross-domain integration and standardization activities of REACH at the event²¹.

CEN/CENELEC Standards+Innovations Awards

In the year 2019, CEN/CENELEC launched the Standards+Innovations Awards²² on 13th November at the European conference "Boosting innovations through standards" to acknowledge outstanding contributions of research and innovation to standardization. CEN/CENELEC national members could nominate their candidates²³. One of the 3 Standards+Innovations Awards was given to an individual who successfully introduced her/his research outcomes or innovations, into standardization, thereby creating an impact for her/his work. DIN took the initiative to nominate Thomas Linner for this award as he unites his research, and standardization on all levels (national, European and international) and is thereby personally active in bringing forward and addressing the more and more critical issue of ageing societies by standardization. During the conference mentioned above, it was announced that Thomas Linner is winning the very first Standards+Innovations Award. As Thomas Linner was leading the ISO/TC 314/WG2 meeting in Sydney from 12th to 14th November, Prof. Bock attended the conference and received the award. Thomas Linner's absence due to the ISO meeting was acknowledged as the most valid reason for one can think of, as instead of attending the conference, he was working on standardization without which he would not have won the award.

Integration of standardization aspects into REACH business model

Standardization was acknowledged during the development of the REACH business models as standards were seen as a creator of a channel to help to shape the customer's relations. The use of standardization in the context of REACH's business models is explained in WP8+9/D35b.

Standardization was included directly into the business model canvases for particular TPs and REACH value propositions. This is valid for the business model of TP 2 Prevention, Activation, Engagement, and Empowerment through Smart ML-enhanced Care/Patient Room, for the business model of T3 Prevention, Activation, Engagement, and Empowerment through Socializing and Nutrition and for the business model of T4 Prevention, Activation, Engagement, and Empowerment through a Gamified Engagement Environment). Elements in the business model canvases related to stakeholders, customers, segments, etc. were adjusted to aspects that are already addressed in national, EU, and international standardization activities.

²¹ Presentation available on:

<https://www.din.de/resource/blob/312646/daaeaa7e5c8d60090de4305284900e1c/presentation-reach-project-data.pdf> [11/08/2019]

²² More information can be found on:

https://www.cencenelec.eu/research/Standards_Innovation_Awards/Pages/default.aspx [01/19/2020]

²³ A list of all nominees can be found on:

<ftp://ftp.cencenelec.eu/EN/ResearchInnovation/StandardsInnovation/ListNominees2019.pdf> [01/19/2020]

Furthermore, in WP7/D30, an overview is provided, and standards utilized in REACH in the context of acceptability, privacy, ethics, and accessibility aspects are listed.

6 Summarization, interpretation, generalization

This Section will summarize the work that has been undertaken related to standardization within the REACH project. The focus will be on the European and international activities and on the advantages of REACH to be involved in standardization.

REACH has the ambition to influence and gain from standardization on national, European, and international levels (see **Figure 6-1**). REACH created synergies between these levels by parallel work that will finally make a beneficial impact. Systematic parallel and synergetic work on these levels allow creating a maximized impact for all involved stakeholders, and in particular, creating better health and health care conditions for potential REACH end users.

Research of existing standards and on-going standardization activities in the relevant fields were undertaken as this is the first main task in the REACH standardization strategy.

Due to a) the recent developments at the national, European, and international standardization level (topics as active ageing, assisted living, and data-driven prevention get much faster and in greater scale recognition in standardization than assumed at the beginning of the project in 2016), and b) the REACH partners high interest and aspirations concerning standardization topics, it is seen as a very promising option to adapt and broaden the standardization activities to increase REACH’s impact in the standardization field.

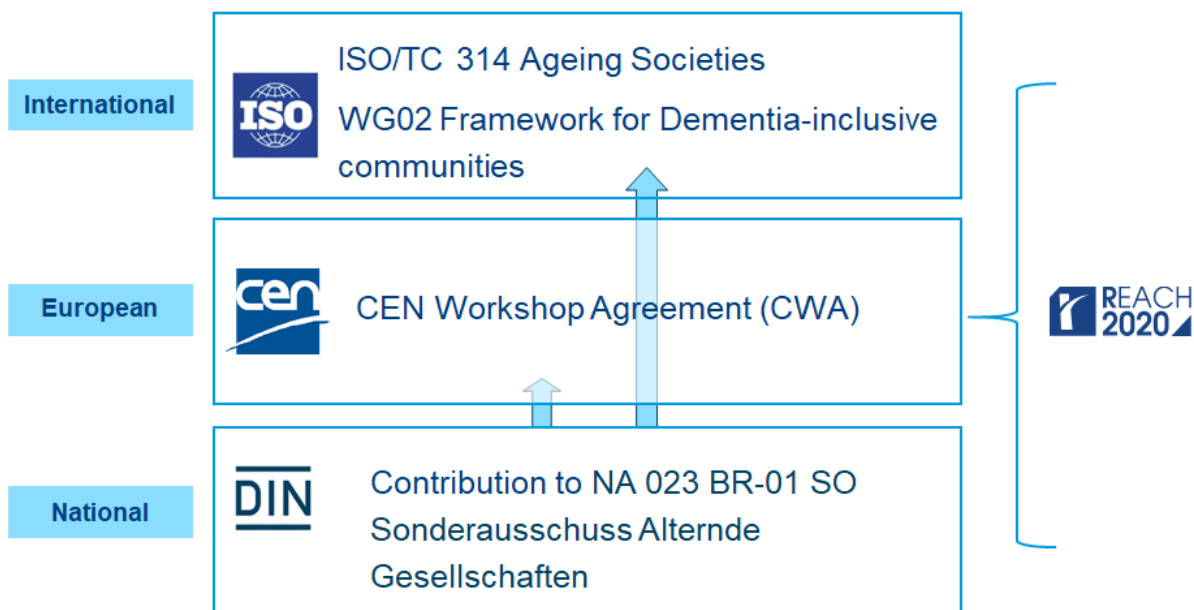


Figure 6-1: REACH contribution on national, European and international Standardization landscape

The partners identified the needs for standardization during the project concerning specific project results achieved at the time and with regards to the existing standards and on-going standardization activities.

This led to the initiation of a European CEN Workshop titled "*Privacy of monitoring technology — Guidelines for introducing ambient and wearable monitoring technologies balancing privacy protection against the need for oversight and care*" was initiated by REACH partners as the partners identified the need of Guidance in this field.

In addition to the initiation of a CEN Workshop Agreement (CWA) on European level, active collaboration on national and international level with the recently founded ISO/TC 314 Ageing Societies (more specifically, with the ISO/TC 314 Working Group 2 (WG02), which works on the ISO/AWI 23623 *Ageing Societies - Framework for Dementia-inclusive communities*) has been undertaken. By contributing to the international standardization activities right from the founding of the new ISO/TC on, the research results and expertise gained by the consortium made a direct impact on the international standardization strategies for addressing the challenges of ageing societies. By this approach, the involvement of European experts has been fostered, as well as that European opinions are heard and shape the results worked out by this WG.

We aim to synchronize the standardization activities on the European and the international level as on the one hand the results of the CWA process was communicated to the ISO/TC 314 WG 2, thus directly feeding into the elaboration of the envisaged framework, and on the other hand, feedback was given back to the project consortium from the standardization community.

Thus, by this high level of interaction with the standardization community, the sustainable transfer of research results into standardization and broad dissemination is exceedingly enhanced.

All in all, it can be summarized that it has various advantages for REACH to contribute to standardization. Worldwide trends and markets could be identified and discussed with the ISO network e.g., dementia and ageing workforce state new potential REACH targets providing scale-up possibilities.

Future standardization activities that are related to the field of ageing can also create a market pull for REACH solutions and can ensure the competitiveness. Thus, the active involvement of REACH partners in standardization even after the duration of the REACH project will support the sustainability and dissemination of the REACH outcomes.

7 References

- [1] Source: The annual Union work programme for European standardization for 2017. Available on: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2016:357:FIN> [01/24/2020]
- [2] Source: <https://www.din.de/en/about-standards/din-standards> [05/11/2020]
- [3] More information can be found on: <https://www.din.de/en/about-standards/din-standards> [01/24/2020]
- [4] Available on: <https://www.beuth.de/de/technische-regel/din-spec-4885/197461551> [01/24/2020]
- [5] EN 45020:2006 Standardization and related activities - General vocabulary (ISO/IEC Guide 2:2004)
- [6] Source: <https://www.din.de/en/about-standards/a-brief-introduction-to-standards>, <https://www.iso.org/member/1511.html> [10-22-2019]
- [7] Source: <https://www.din.de/en/din-and-our-partners/din-in-europe/european-standardization>. [10-23-2019]
- [8] Source: <https://www.din.de/en/getting-involved/standards-committees> [10-28-2019]
- [9] An official presentation of ISO/TC 314 can be found in Appendix 8.10.
- [10] Source: <https://www.iso.org/who-develops-standards.html> [10-28-2019]
- [11] IWA 18 can be found on: <https://www.iso.org/obp/ui/#iso:std:iso:iwa:18:ed-1:v1:en> [10-25-2019]
- [12] ISO/TC 314 committee website: <https://committee.iso.org/home/tc314> [12-14-2019]
- [13] Available on: ftp://ftp.cencenelec.eu/EN/EuropeanStandardization/Guides/29_CENCLCGuide29.pdf [01-25-2020]
- [14] Source: <https://www.cencenelec.eu/news/workshops/Pages/default.aspx> [01-25-2020]
- [15] CWA download area available on: <https://www.cencenelec.eu/research/CWA/Pages/default.aspx> [01-09-2020]
- [16] CEN/WS 102 project plan, see Appendix 8.4
- [17] Project website: <https://progressivestandards.org/> [12/13/2019]
- [18] Source: <http://reach2020.eu/?p=2866> [01/25/2020]

[19] Available on: <https://progressivestandards.org/wp-content/uploads/2019/01/Guidelines-for-standards-around-ICT-for-AHA-for-age-friendly-smart-homes.pdf> [12/13/2019]

[20] More information can be found on: <https://www.din.de/de/din-und-seine-partner/public-affairs/aktuelles/standards-helfen-forschungsergebnisse-zu-verbreiten-und-marktfaehig-zu-machen-312696> [11/08/2019]

[21] Presentation available on: <https://www.din.de/resource/blob/312646/daaeea7e5c8d60090de4305284900e1c/presentation-reach-project-data.pdf> [11/08/2019]

[22] More information can be found on: https://www.cencenelec.eu/research/Standards_Innovation_Awards/Pages/default.aspx [01/19/2020]

[23] A list of all nominees can be found on: <ftp://ftp.cencenelec.eu/EN/ResearchInnovation/StandardsInnovation/ListNominees2019.pdf> [01/19/2020]

8 Appendix

8.1 List of relevant standards and literature

8.1.1 *Facilitation of the use of standards within REACH*

Key aspects (draft):

8.1.2 *Ethical, social, and inclusion dimensions*

- a) ISO 26000 Guidance on Social Responsibility
- b) WHO Screening criteria and good practices (e.g. Wilson and Jungner and updated versions)²⁴
- c) CWA 17145-1:2017 (WI=WSSAT001) Ethics assessment for research and innovation - Part 1: Ethics committee
- d) ISO/ DTS 17033 Ethical claims and supporting information – principles and requirements
- e) IWA 18:2016 Framework for integrated community-based life-long health and care services in aged societies
- f) ISO TC 314 Ageing societies: WG1 – Ageing workforce ; WG2 - Dementia inclusive
- g) ISO/TR 22221:2006 Health informatics — good principles and practices for a clinical data warehouse

8.1.3 *Privacy aspects*

- a) The EU's General Data Protection Regulation (GDPR)²⁵
- b) The OECD privacy framework²⁶
- c) CEN/CLC/JTC 8 Privacy management in products and services
- d) ISO/IEC 20889:2018 Privacy enhancing data de-identification terminology and classification of techniques
- e) ISO/NP 31700 Consumer protection - privacy by design for consumer goods and services
- f) ISO/AWI 22697 Health informatics - application of privacy management to personal health information
- g) ISO/IEC 29100:2011 Information technology – security techniques – privacy framework
- h) ISO/IEC 29101:2018 Information technology – security techniques - privacy architecture framework
- i) ISO/TR 18638:2017 Health informatics – guidance on health information privacy education in healthcare organisations
- j) ISO/IEC AWI 27030 Information technology – security techniques – guidelines for security and privacy in Internet of things

²⁴ Available on: <https://www.who.int/bulletin/volumes/86/4/07-050112/en/>

²⁵ Available on: <https://gdpr-info.eu/>

²⁶ Available on: http://www.oecd.org/sti/ieconomy/oecd_privacy_framework.pdf

8.1.4 *Legal and liability aspects*

- a) ISO 14155:2011 Clinical investigation of medical devices for human subjects – good clinical practice
- b) IEC/ISO 31010:2019 Risk management - Risk assessment techniques
- c) ISO 31000:2018 Risk management - Guidelines
- d) ISO 13485:2016 Medical devices - Quality management systems -- Requirements for regulatory purposes
- e) National medical devices laws (e.g. German Medizinproduktegesetz: MPG)
- f) European MDD (Medical Device Directive), 93/42/EEC -includes regulations on medical CE marking, etc.²⁷
- g) Clinical Evaluation Report (CER) according to MEDDEV 2.7/1 rev4 and MDD (or MDR)^{28 29}

8.1.5 *Usability, accessibility and acceptability*

- a) EN ISO 9241-161:2016 (WI=00122208)
Ergonomics of human-system interaction - Part 161: Guidance on visual user-interface elements (ISO 9241-161:2016)
- b) EN ISO 9241-11:2018 (WI=00122223)
Ergonomics of human-system interaction - Part 11: Usability: Definitions and concepts (ISO 9241-11:2018)
- c) ISO 21542:2011 Building construction - Accessibility and usability of the built environment
- d) ISO TC 136 Furniture
- e) ISO/IEC JTC 1/SC 35 User Interfaces
- f) ISO/TS 20282-2:2013 Usability of consumer products and products for public use - Part 2: Summative test method
- g) ISO/TR 16982:2002 Ergonomics of human-system interaction - Usability methods supporting human-centred design
- h) IEC 62366-1:2015 Medical devices - Part 1: Application of usability engineering to medical devices
- i) ISO 9241-960:2017 Ergonomics of human-system interaction - Part 960: Framework and guidance for gesture interactions
- j) ISO/IEC TR 29138-3:2009 Information technology - Accessibility considerations for people with disabilities - Part 3: Guidance on user needs mapping
- k) ISO/DIS 21801 General guidelines on cognitive accessibility
- l) ISO/CD 24552 Ergonomics - Accessible design - Accessibility of information presented on visual displays of small consumer products
- m) ISO/IEC 29138-1:2018 Information technology - User interface accessibility - Part 1: User accessibility needs

²⁷ Available on: <https://eur-lex.europa.eu/eli/dir/1993/42/oj>

²⁸ Available on: <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32017R0745&from=EN>

²⁹ Available on: <http://ec.europa.eu/DocsRoom/documents/17522/attachments/1/translations/en/renditions/native>

8.1.6 Data formats, platforms, ICT elements

- a) IEC SyC AAL
- b) Open mHealth data schemata³⁰

8.2 CWA Project plan



2019-07-11

Project Plan for the CEN Workshop on guidelines for introducing tele-medical and pervasive monitoring technologies balancing privacy protection against the need for oversight and care

1. Status of the Project Plan

- Initial draft Project Plan, to be further developed, prior to submission for approval
- Draft Project Plan to be approved at the Kick-off meeting of the Workshop
- Approved Project Plan

2. Background to the Workshop

2.1. Introduction to REACH project

The health expenditure in the EU is expected to rise by 350% by 2050 compared to an economic expansion of only 180% and the provision of Long Term Care (LTC) will pose an increasing challenge to the sustainability of public finances in the EU, due to an ageing population. REACH¹ therefore represents a solution that seeks to prevent elderly citizens from loss of function and a decline of being able to perform Activities of Daily Living (ADLs) independently leading ultimately to entering LTC. REACH is a personalized prevention and intervention system that promotes the activity of the elderly by monitoring and evaluating their daily habits, considering both personal medical history as well as real-time gathered data from a series of wearable and embedded sensors, in order to mitigate loss of function and to arrest associated and/or consequential morbidities via a number of physical and virtual activity intervention modules. REACH is an open solution that proposes its own innovative systems while remaining compatible with existing sensing systems and technologies². In this context, it is recognized that guidance is needed to balance privacy against the need for oversight and care.

2.2. Motivation for the Creation of this Workshop

The GDPR and European national legislations impose limitations on introducing technologies that enable professional and informal care providers to monitor continuous information on a person's activities and actions even when such monitoring is conducted for the purpose of care.

¹ More information on the REACH (Responsive Engagement of the Elderly promoting Activity and Customized Healthcare) project can be found under: <http://reach2020.eu/>

² Source: <https://cordis.europa.eu/project/rcn/200425/factsheet/en>

³⁰ Available on: <https://www.openmhealth.org/documentation/#/overview/get-started>
Responsive Engagement of the Elderly promoting Activity and Customized Healthcare

8.3 ISO/TC 314 Presentation

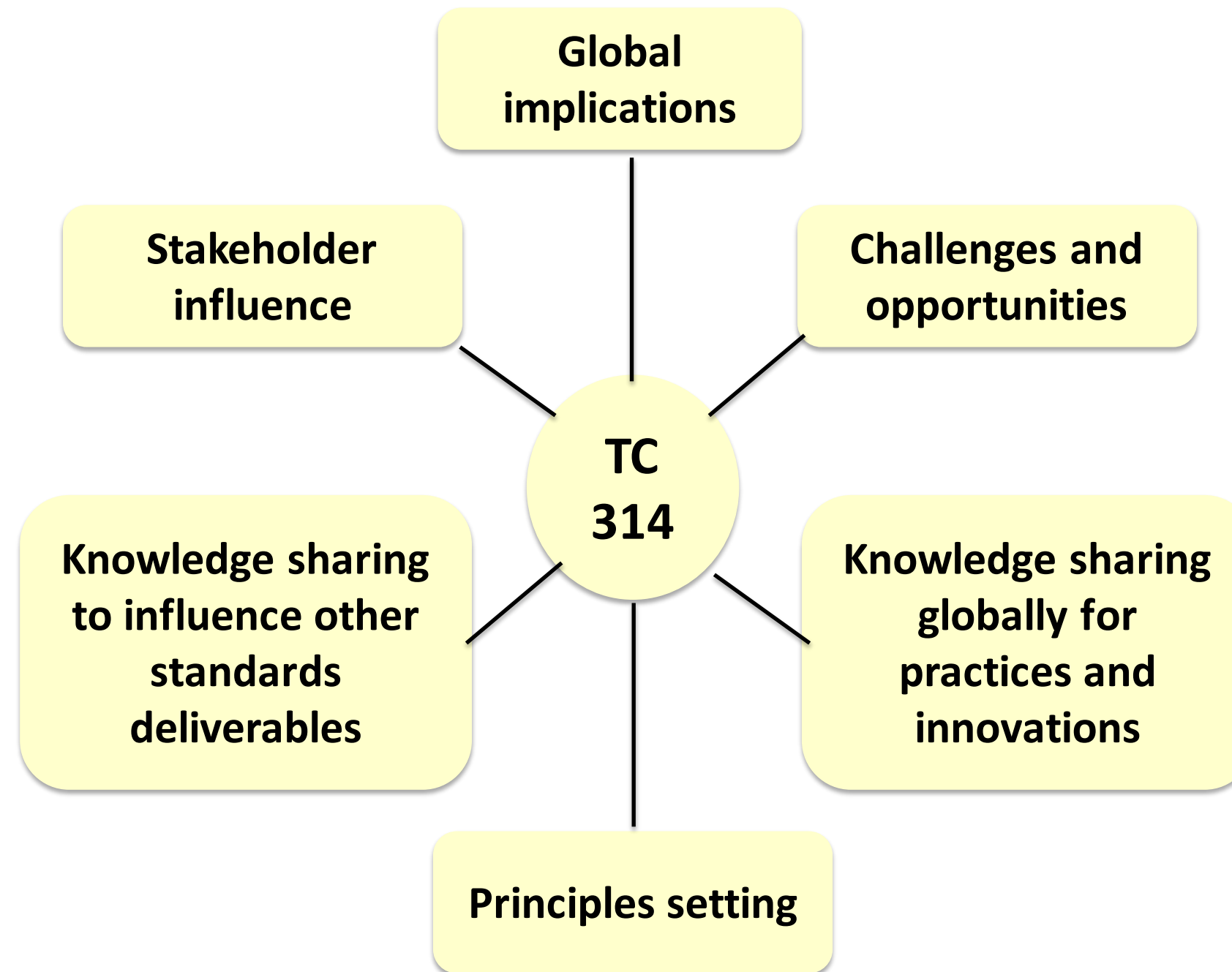
See next pages.

INTRODUCTION TO TC314 WORK



SCOPE ISO/TC 314

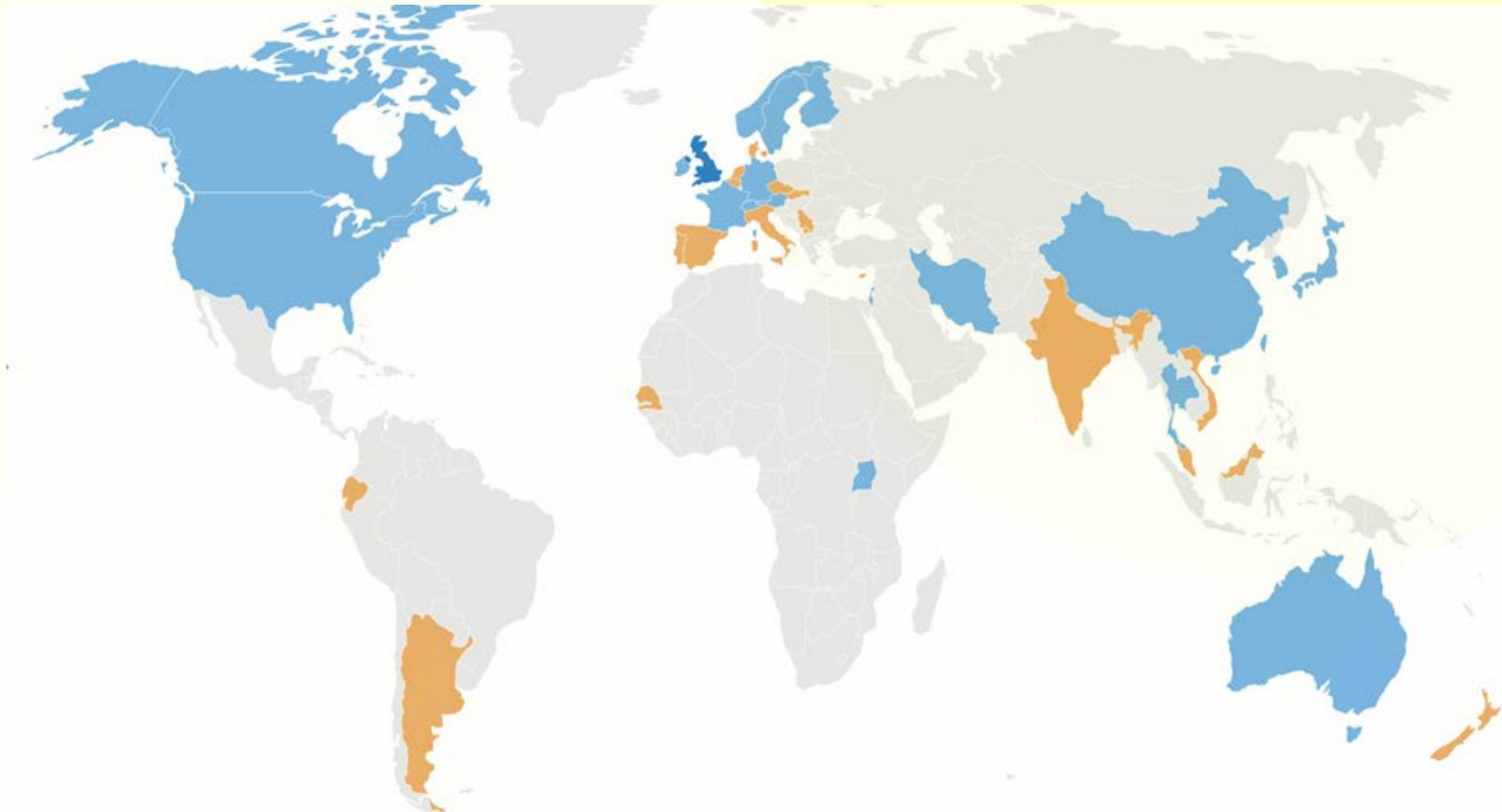
Standardization in the field of ageing societies



Stakeholder benefits

- Older persons and their families
- Service providers
- Product manufacturers
- Research bodies
- Healthcare specialists
- Carers
- Organizations
- Governments
- Communities

COMMITTEE ISO/TC 314



LIST OF MEMBERS*

Chair –Britta Berge

- Australia
- Austria
- Canada
- China
- Finland
- France
- Germany
- Iran
- Ireland
- Israel
- Japan
- Korea
- Norway
- Singapore
- Switzerland
- Sweden
- Thailand
- United Kingdom
- Uganda
- United States

* Member list is subject to change.

COMPONENTS

ISO/TC 314

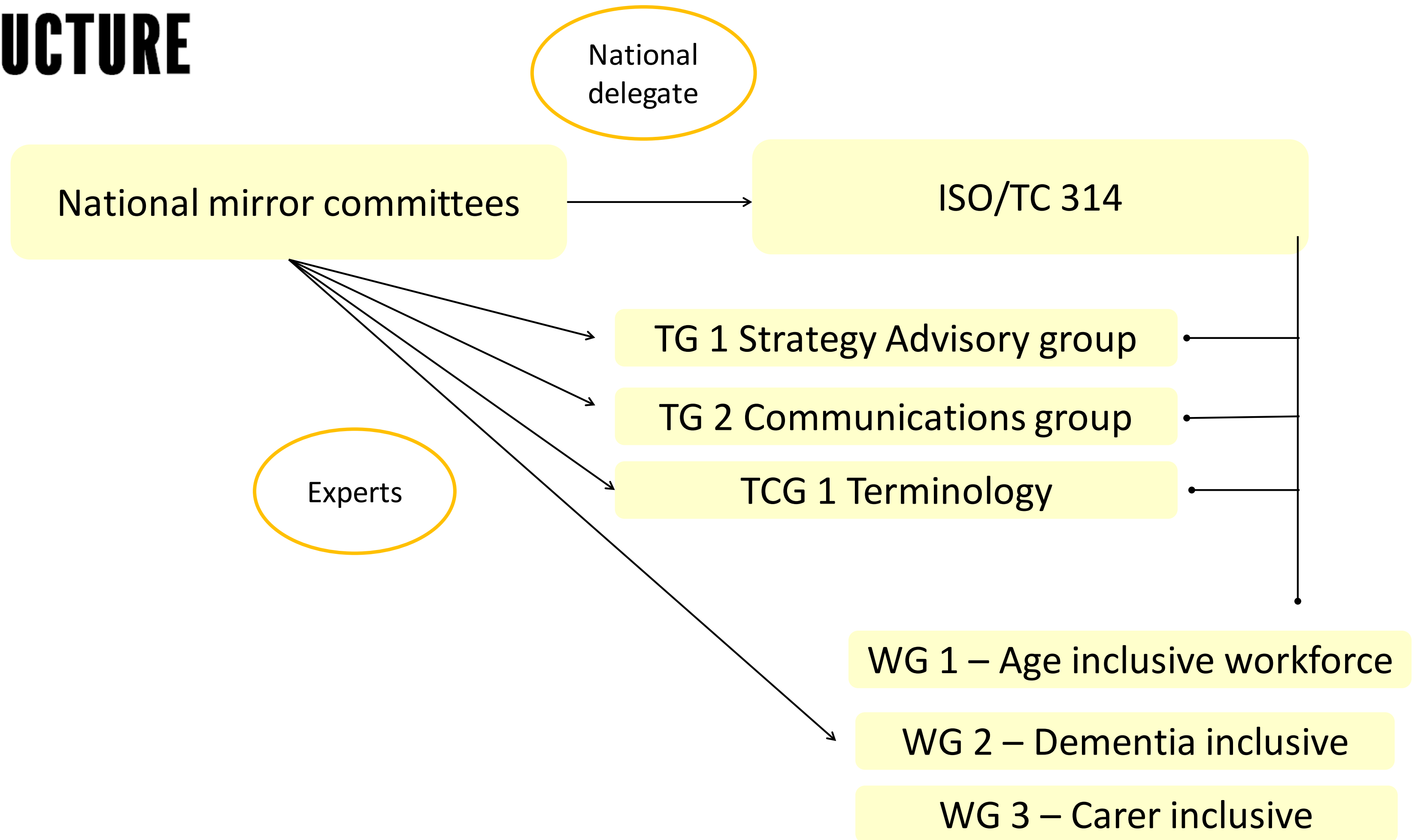
Primary priority

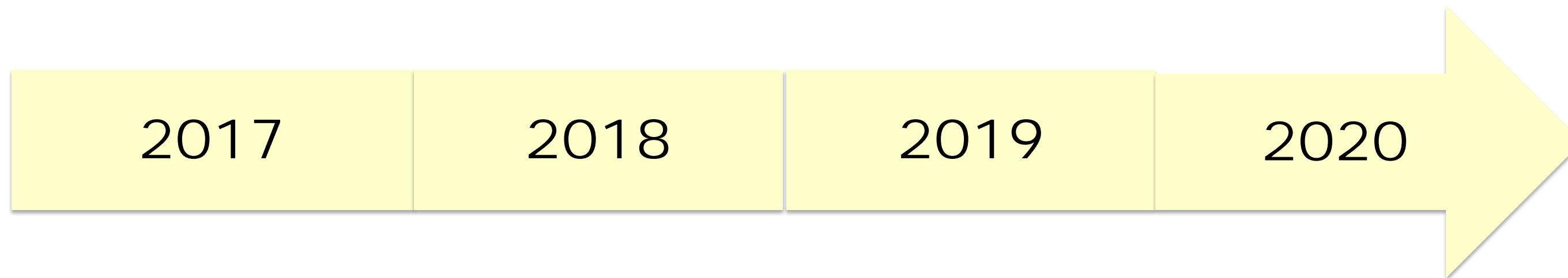
- Dementia inclusive
- Ageing Workforce
- Carer inclusive
- Health promotion and preventative care in older age
- Social connectedness
- Communities with multi-generational people

Lower priority

- Universal design
- Accessibility
- Technologies and systems for an ageing society

STRUCTURE





December 2017
ISO/TC 314 was established

June 2018
First plenary meeting

Agreement on first 2 work items

November 2018
Second plenary meeting

Announcement 3rd work item

June 2019
3rd plenary meeting

Agreement strategic business plan until 2020

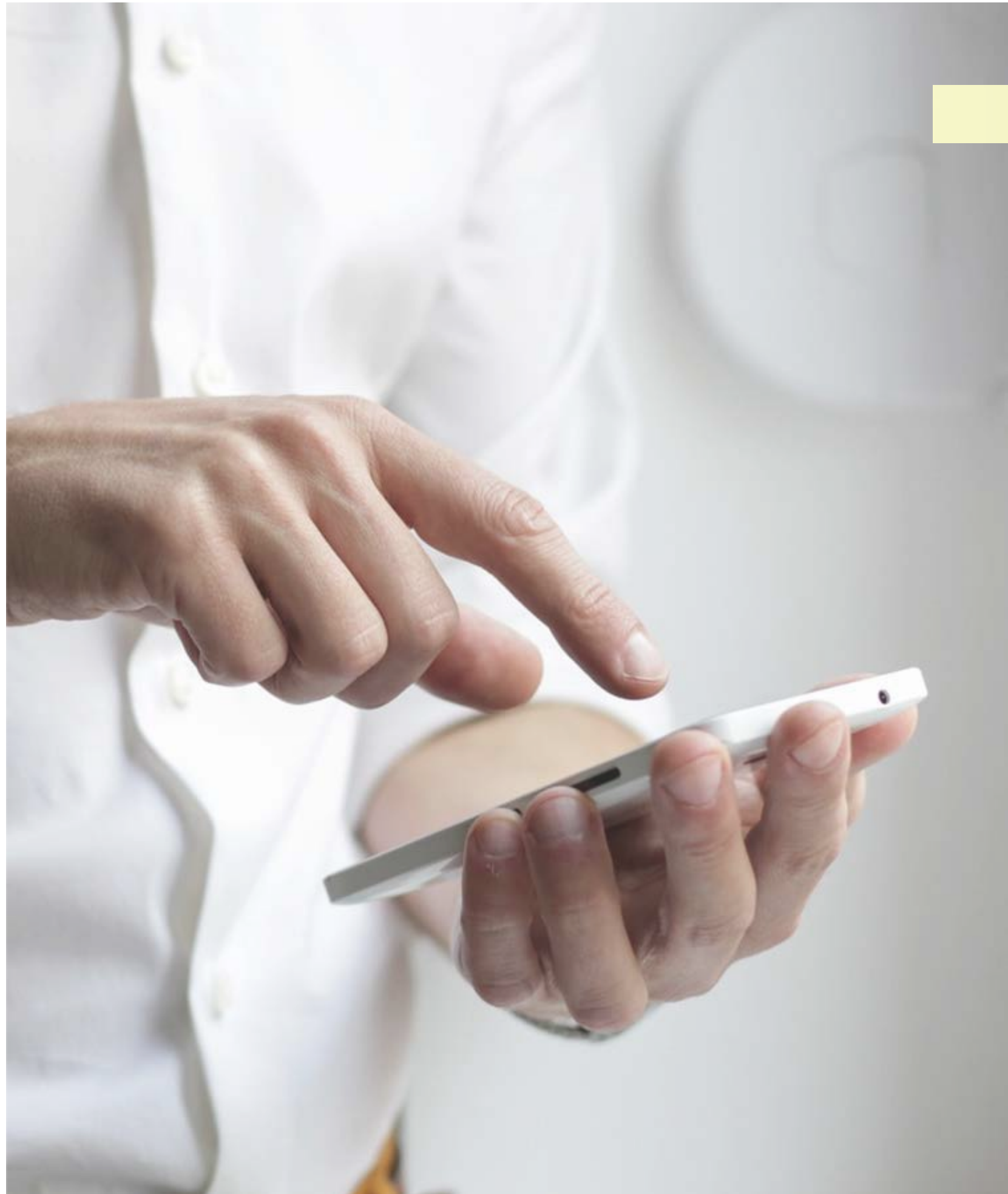
November 2019
4th plenary meeting

2020
5th plenary meeting

Adjustment strategic business plan to review priority areas

Potentially new work items

Internal document for agreed terminology



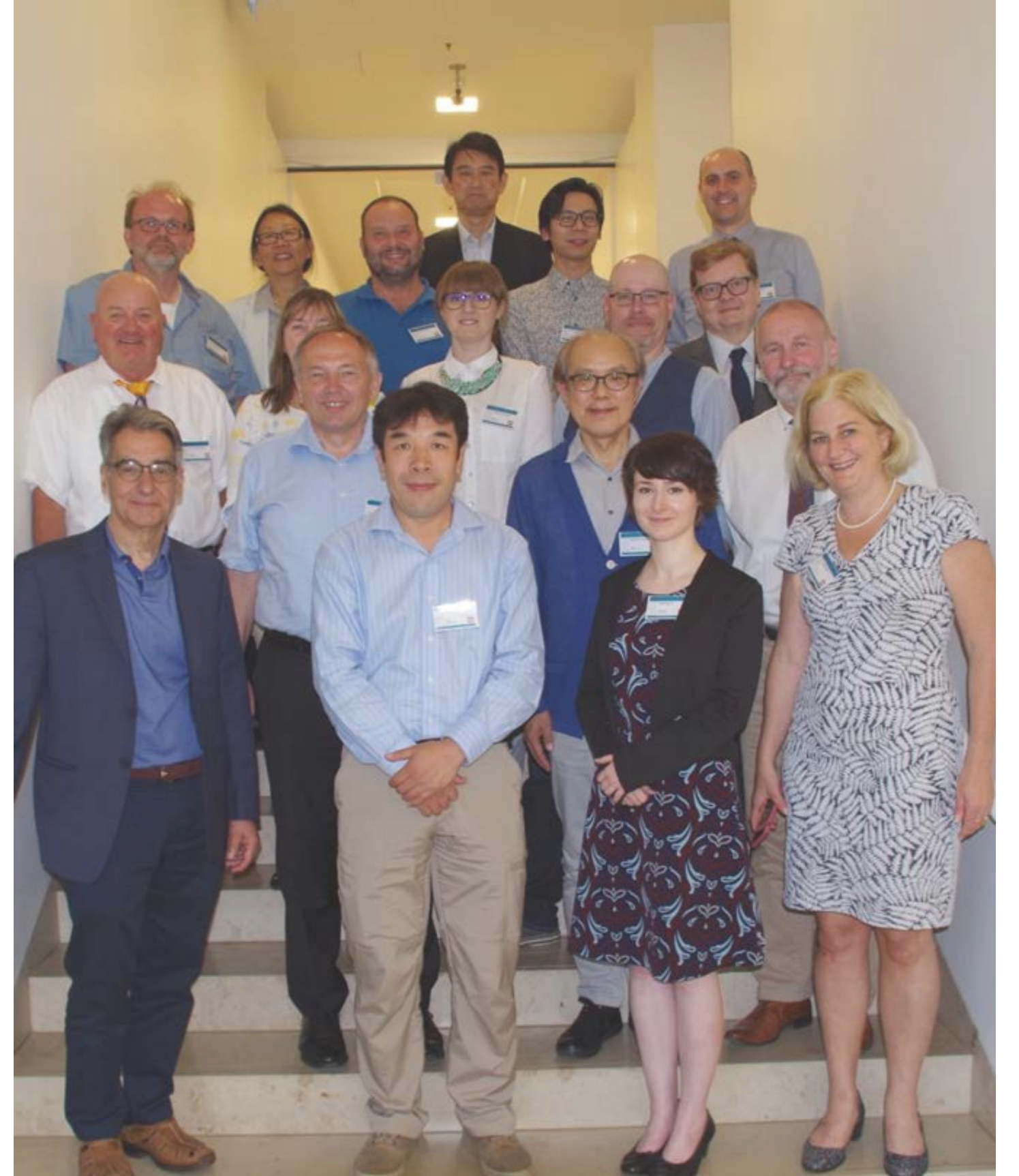
Nele Zgavc

Nele.Zgavc@bsigroup.com



TC 314/WG1

GUIDELINES FOR AN AGE INCLUSIVE WORKFORCE





SCOPE

TC314/WG1

— Provides guidelines and recommendations that allows organisations to develop, implement and maintain an ageing older inclusive workforce; and

— This includes all phases of the worker life cycle from beginning through retirement as well as opportunities for older workers to continue working and changing careers.

Adds value to both the organisation and the older worker;

Contributes to SDG Goals

The perceived benefits for the various stakeholder groups were identified at several International meetings.



Example stakeholder benefit ‘Governments/Communities:

- 1. National governments:** able to exchange and promote national objectives for ageing society initiatives including seeking common solutions together with other nations.
- 2. Local communities:** support development of policy measures to be inclusive to live with of older persons while sustaining vitality and attractiveness of the community.
- 3. Increased participation reduces social isolation** and improves wellbeing with less reliance on government spending and generates an increased tax revenue
- 4. Standards can support measures to make it easier for older workers to actively participate and stay in the labour market and strengthen a culture of responsibility, commitment, respect and dignity in all workplaces where all workers are valued as important irrespective of age.**



**NEED
TC314/WG 1**



COMMITTEE TC314/ WG 1

LIST OF MEMEMBERS

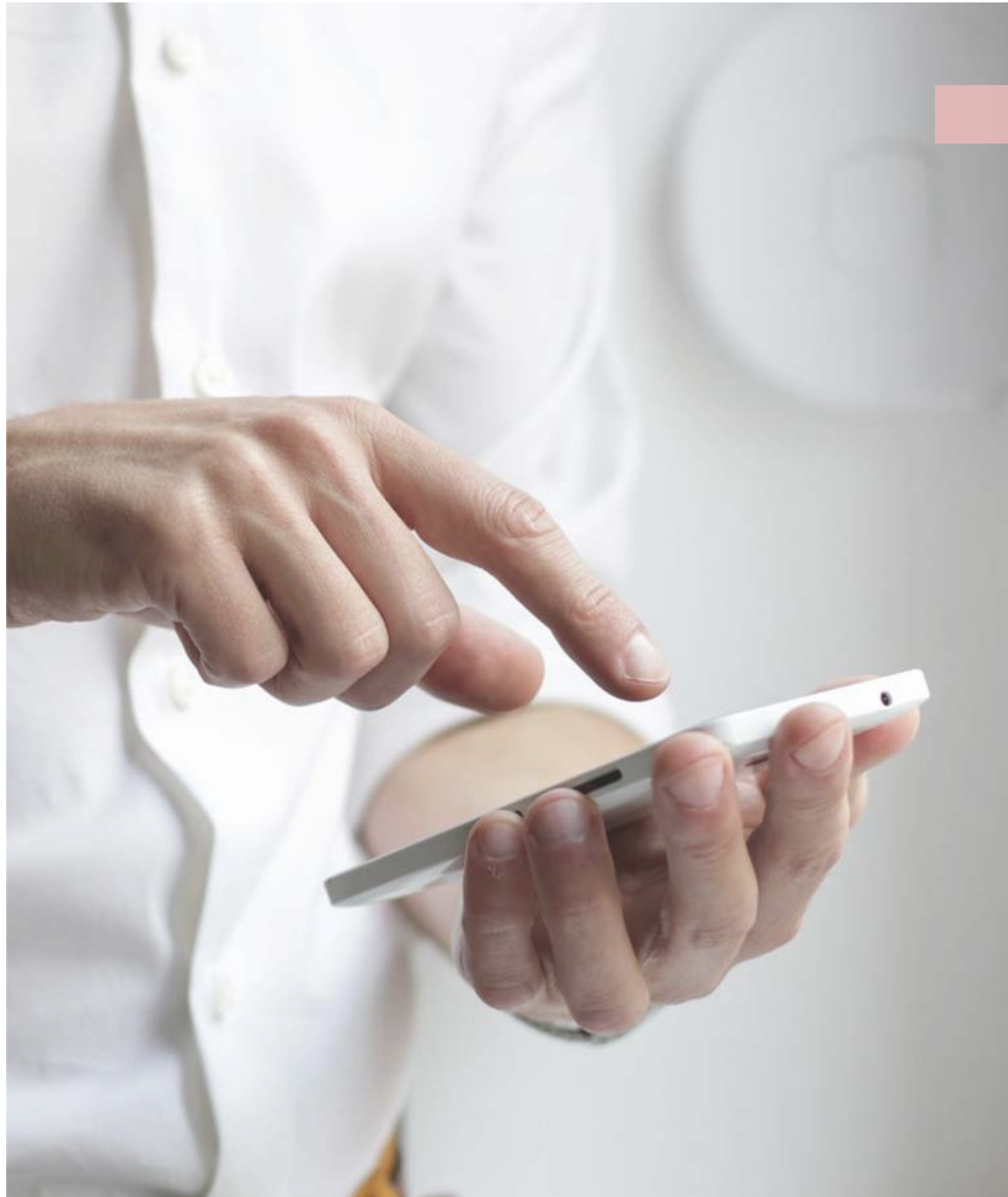
Convenor -Dr Sabrina Pit

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- **Singapore**
- **Switzerland**
- **Sweden**
- **Thailand**
- **United Kingdom**
- **Uganda**
- **United States**

TIMEFRAMES AND NEXT STEPS

ISO 23623 Ageing Societies - Guidelines for an age inclusive work force

- Development began in October 2018;
- Committee draft comment early 2020;
- Public comment late 2020; and
- Publication expected approximately in November 2021.



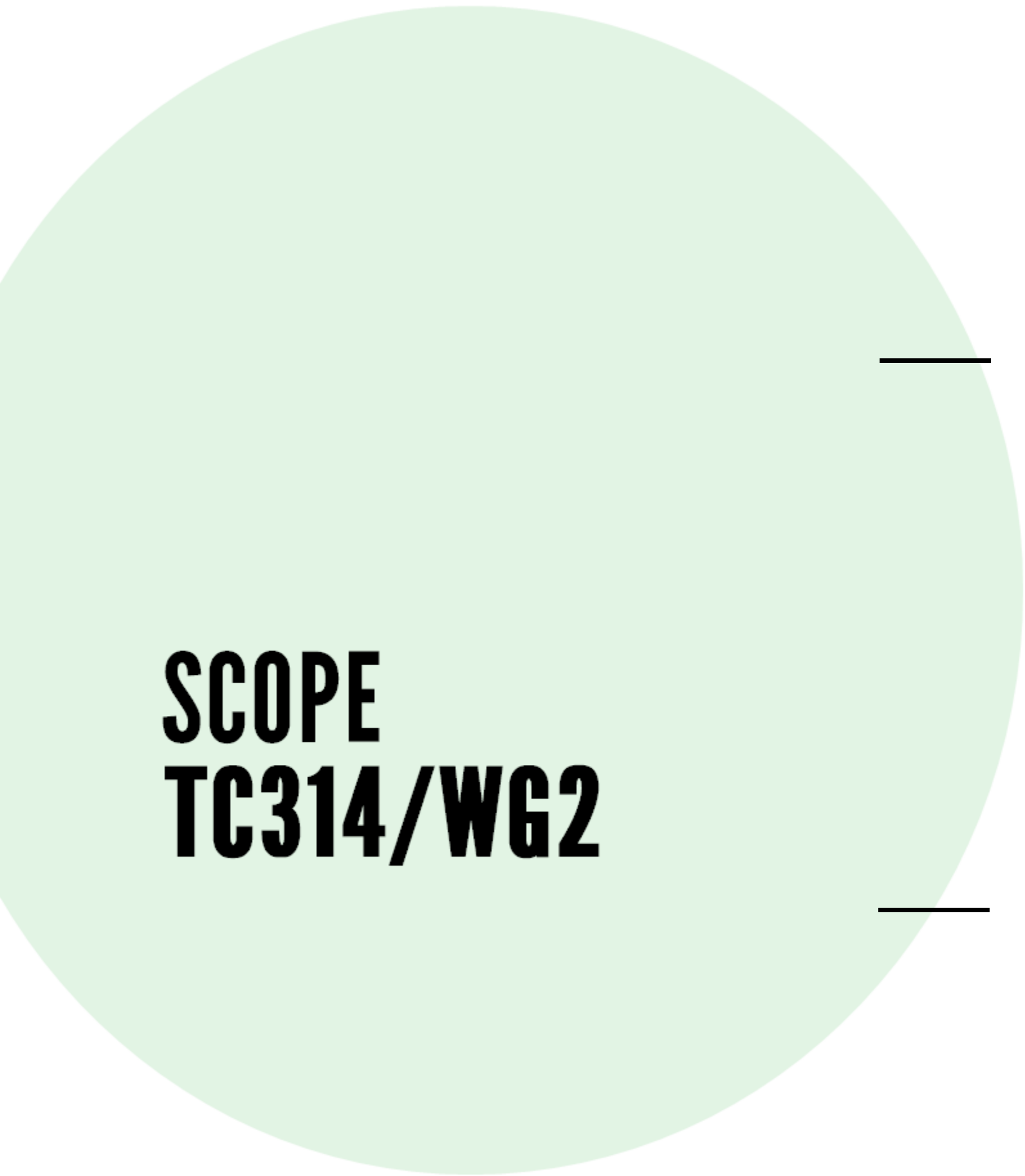
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TC 314/WG2

FRAMEWORKS FOR DEMENTIA INCLUSIVE COMMUNITIES





**SCOPE
TC314/WG2**

Provides a framework for dementia-inclusive communities including principles and considerations of inclusion, quality of life, built environments, special needs groups and stakeholder engagement; and

Aims to promote further standards development and collaboration with service providers, standards markers and other interested parties.

COMMITTEE TC314/ WG 2

LIST OF MEMBERS

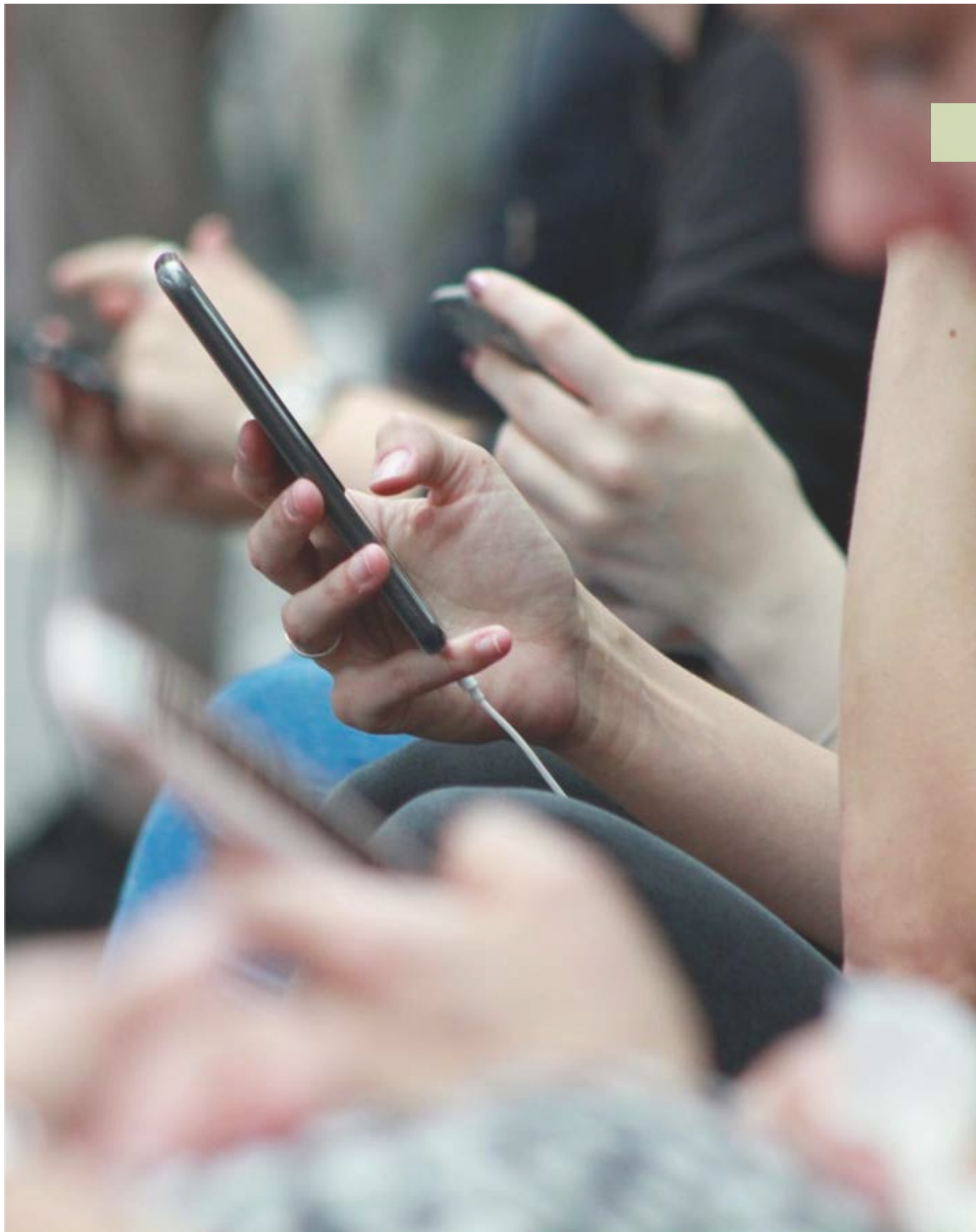
Convenor -Dr Thomas Linner

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- **Sweden**
- **Thailand**
- **United Kingdom**
- **Uganda**
- **United States**

TIMEFRAMES AND NEXT STEPS

ISO 23617 Ageing societies - Framework for Dementia-inclusive communities

- Development began in October 2018;
- Committee draft comment early 2020;
- Public comment late 2020; and
- Publication expected approximately in November 2021.



Dr Thomas Linner

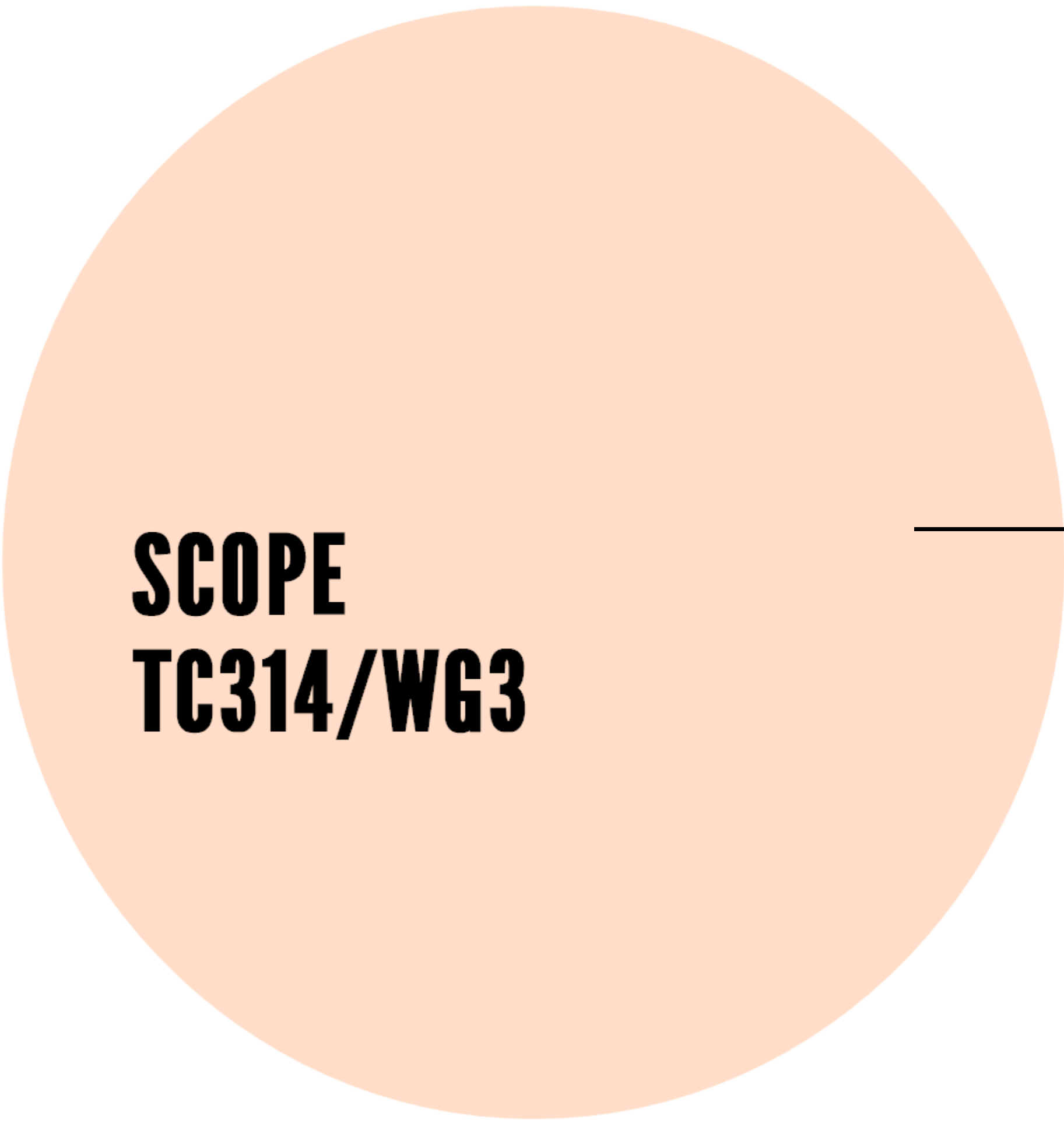
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TC 314/WG3

**CARER INCLUSIVE AND ACCOMMODATING
ORGANISATIONS**





SCOPE
TC314/WG3

Caregiver-employees are defined as individuals who participate in paid employment while also providing unpaid care for an adult dependent.

By 2050, 1 in 6 people will be over the age of 65 globally;

World's ageing population has unique impacts on the global labour force, particularly contributing to the growing number of caregiver-employees (CEs);

Given the gendered nature of care work across the globe, the majority of carer-employees are female; this is particularly the case in developing world context; and

There are currently no international standards addressing the topic of carer-inclusive and accommodating workplaces.



**NEED
TC314/WG3**



**COMMITTEE
TC314/ WG 3**

LIST OF MEMBERS

Convenor –Alison Williams

- **Australia**
- **Canada**
- **China**
- **Finland**
- **Singapore**
- **Sweden**
- **United Kingdom**
- **Uganda**
- **United States**

COMPONENTS TC314/WG3

- **Access the need of the organisation and workers;**
- **Address and ensure confidentiality for workers;**
- **Provide training to management;**
- **Create awareness campaigns for management and workers;**
- **Develop a 'carer culture'; and**
- **Offer accommodation (Flexible work hours and locations, Cell-phone use at work, Providing leave from work, Monitor and measure results of these policies and efforts and conduct an annual internal audit of these policies and efforts).**

TIMEFRAMES AND NEXT STEPS

ISO 23889 Ageing societies - Carer-inclusive and accommodating organisations

- Development began in May 2019;
- Publication expected in the second quarter 2022;
- The standard will provide a set of guidelines for employers to better accommodate family carers who are simultaneously juggling employment; and
- Structure based on CSAB701-17 Carer-Inclusive and accommodating organisations.