# SIGNET

**S**ensing and **I**mage-**G**uided **N**eurological therapies, cardiac **E**lectrophysiology and **T**umour treatments

ITEA4 Project Number 20052

# D6.1 – Dissemination and Standardization Plan

Due date of deliverable: 30th June 2022
Actual date of submission: 17th June 2022

**Start date of project: 1 November 2021** **Duration:** 36 months

**Organisation name of lead contractor for this deliverable:** Philips Medical Systems Nederland B.V.

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**Version number:** 1.0

**Doc reference:** SIGNET_D6.1-Dissemination and Standardization Plan

**Work Pack./ Task:** WP6

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|---|---|---|---|
| **Nature:** | R | | |
| **Dissemination Level:** | **PU** | Public | **x** |
| | **PP** | Restricted to other programme participants | |
| | **RE** | Restricted to a group specified by the consortium | |
| | **CO** | Confidential, only for members of the consortium | |

**DOCUMENT HISTORY**

| Release | Date | Reason of change | Status | Author |
|---|---|---|---|---|
| V0.1 | 28/02/2022 | First draft | Draft | Saurav Kumar Baidya |
| V0.2 | 13/03/2022 | Updated both dissemination and standardization sections | Draft | Johan van den Brink |
| V0.3 | 21/04/2022 | Further updates on the entire document | Review | Saurav Kumar Baidya |
| V1.0 | 17/06/2022 | Updates based on review comments | Final | Saurav Kumar Baidya |

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# Glossary

| | |
|---|---|
| AI | Artificial Intelligence |
| IEC | International Electrical Committee |
| ISO | International Standards Organization |
| ML | Machine Learning |
| SDO | Standards Development Organization |

# Executive Summary

This document describes the plan for using and disseminating the knowledge in the context of the SIGNET project, through various means including internal and external communication channels, the distribution of dissemination material and participation in dissemination activities. More specifically, the document includes

- SIGNET's dissemination strategy, describing the target audience active in verification and validation of evolving systems and the means for communicating with them
- planned and performed dissemination activities will be recorded over the course of the project, including the participation in conferences and other relevant events and the publications in scientific journals.
- SIGNET's contributions to standards development in the realm of Magnetic Resonance image-guided therapy, covering applicable IEC medical equipment standards, ASTM standards related to MR compatibility, NEMA standards for MR equipment and certain sub-parts of medical image interfacing standard DICOM. Also horizontal and vertical standards and regulations for Artificial Intelligence will be covered (ISO, BSI, IEC), including the EU AI Act.

This document does not describe the COMRADE-based systems-of-systems integrations, because WP5 (Use Cases and Demonstrators) is fully dedicated to this important dissemination topic.

# 1. Introduction

Dissemination is an important element of the SIGNET project. It will be carefully planned and implemented in order to spread awareness about this ITEA4 project to a wide audience, including its end-users. This will help guarantee an optimal exploitation of the project results and the long-term sustainability of the SIGNET vision. For this reason, the SIGNET participants have formulated dissemination plan that describes the objectives and foreseen channels for the dissemination of the knowledge generated by the project.

This plan is in compliance with the SIGNET full project proposal CR#2[1] (ITEA4 20052), the SIGNET Project Consortium Agreement[2], and the ITEA Rules and Regulations version 20, September 2021. This plan will be revised as the need arises and on Month 36 of the project a final report on the dissemination and standardization activities will be published (D6.3 Report on Standardization, Dissemination and Exploitation).

[1] CR#2 is in preparation in parallel to this deliverable.
[2] PCA is works in progress.

***Table 1: List of SIGNET Participants***

| No | Partners | Country |
|---|---|---|
| 1 | Academic Medical Center of the University of Amsterdam (AMC) | NLD |
| 2 | Brain Science Tools B.V. | NLD |
| 3 | Braincarta B.V. | NLD |
| 4 | LifeTec Group B.V. | NLD |
| 5 | Machnet Medical Robotics B.V. | NLD |
| 6 | Philips Electronics Nederland B.V. | NLD |
| 7 | Philips Medical Systems Nederland B.V. | NLD |
| 8 | UMC Utrecht | NLD |
| 9 | Adas3D Medical SL | ESP |
| 10 | Galgo Medical SL | ESP |
| 11 | Imeka | CAN |
| 12 | Modus Medical Devices Inc. | CAN |

# 2. Dissemination strategy

## 2.1 Means of communication

In order for dissemination to be effective, multiple communication channels are used in order to be able to effectively reach the desired target audiences. One focus of dissemination will be on scientific publications and to address the academic research community. Publications within the area of interest of the project include both technology oriented journals and conferences. Results to be published will naturally tend to fall into one of the two categories, with some overlap between the two in case conference proceedings are published as journal paper.

Several important target audiences for dissemination activities have been identified; these include academic researchers, manufacturers, maintenance providers, service providers as well as the general public. Different dissemination products are expected to appeal differently to each of these categories, and therefore it is necessary to be aware of what the focus of dissemination is expected to be during the different stages of the project, and how the results to be disseminated are to be best tailored to their target audience.

## 2.2 Timing

Concerning the timing of our dissemination strategy, three distinct phases of implementation can be identified (**Error! Reference source not found.**).

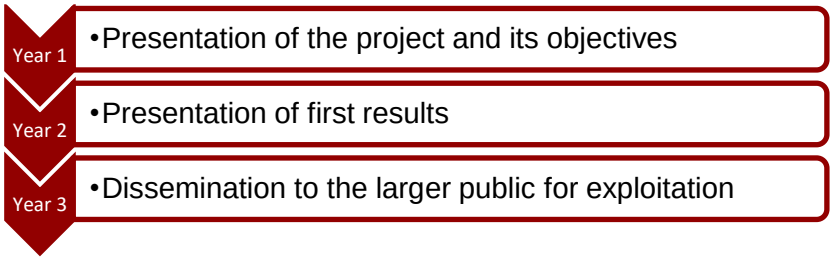


***Figure 1: Focus of dissemination activities shifts over time.***

Early on, focus will lie on building general awareness among industry and the general public, including potential customers, generating interest by communicating application scenarios that appeal to a broad audience. As the project progresses, focus will also encompass the smart services and tools that are being developed.

## 2.3 Internal dissemination strategy

Continuous and effective internal communication is key to the success of international projects such as SIGNET. For this reason, internal dissemination is considered as an essential part of the dissemination strategy as a whole, in particular because partners joined to learn from each-other. Internal communication allows to:

- Keep track of project-related decisions and action points;
- Clearly communicate the role and responsibility of each project participant;

- Communicate on WP and demonstrator progress;
- Disseminate the right level of information to project participants;
- Identify problems and provide solutions.

## 2.4 External dissemination strategy

Much of the effort is aimed at ‘external communication’ to promote the project, and disseminate results. The major external dissemination objectives are to:

- Effectively use these communication channels to present the SIGNET project’s results;
- Establish links and encourage synergies with similar projects and initiatives;
- Provide the foundation of a comprehensive exploitation strategy.

Details of each dissemination activity/tool are provided in the section 4 (“Dissemination Tools”)

# 3. Dissemination rules

## 3.1 Presentation and publication guidelines

All Partners will actively contribute to the publication policy, both at own initiative and upon request of other partners, work package leaders and the project managers.

When another partner is mentioned in a publication, written permission shall be requested from this specific partner. If a partner wishes to publish information generated in the SIGNET project the approval of all partners has to be requested:

- This request shall be made preferably per e-mail;
- Reactions should be sent within 7 days;
- Without reaction permission is automatically granted after 7 days;
- In case of non-unanimous reactions the PM will take the final decision;
- A copy has to be sent of the final publication to the project office for central archiving.
- The document will be published on the website until written indication is given that this is not allowed (e.g. due copyright rules from journals). In this case only the reference will be added.

## 3.2 Graphic identity

This section describes the features that contribute to giving a common graphic identity to all dissemination activities allowing for a better visibility and recognition of the project.

### 3.2.1 Layout and templates

Common/similar ***layouts*** are used for the SIGNET dissemination materials. ***Templates*** for project meeting minutes, deliverables and PowerPoint presentations were made available at the end of Month 2 of the project by the project coordinator, Philips.

### 3.2.2 Logos

In addition to the SIGNET project logo the ITEA4 logo should be used when possible (both are shown on the frontpage of this document.

## 3.3 Compulsory acknowledgements

Any partner in the SIGNET project will in their dissemination activities clearly acknowledge the ITEA4 Program with reference to the project “SIGNET” and the project number 20052.

Preferred reference:

| |
|---|
| *"This work was labelled by ITEA and funded by local authorities under grant agreement "ITEA-2021-20052-SIGNET"* |
| +include link to the project website and where appropriate to the online experimentation platform |

# 4. Dissemination tools

## 4.1 Internal dissemination tools

The project coordinator, Philips (NLD), together with the respective work package leaders, has put in place a variety of mechanisms to optimize the communication workflow.

### 4.1.1 Project meetings

As detailed in the SIGNET FPP CR#2, there are several types of project meetings[3]:

- General Assembly meetings taking place at least three times a year;
- Regular project management team meetings;
- Regular work package meetings;
- Technical workshops;
- Additional telephone when needed for day-to-day coordination of the project.

At the moment of writing of this document so far 1 general assembly meeting[4] have been organized. An impression of these meetings is given in Figure 2. **Error! Reference source not found.**The General assembly meetings serve to update each other on project results, and to align the activities for the next period.

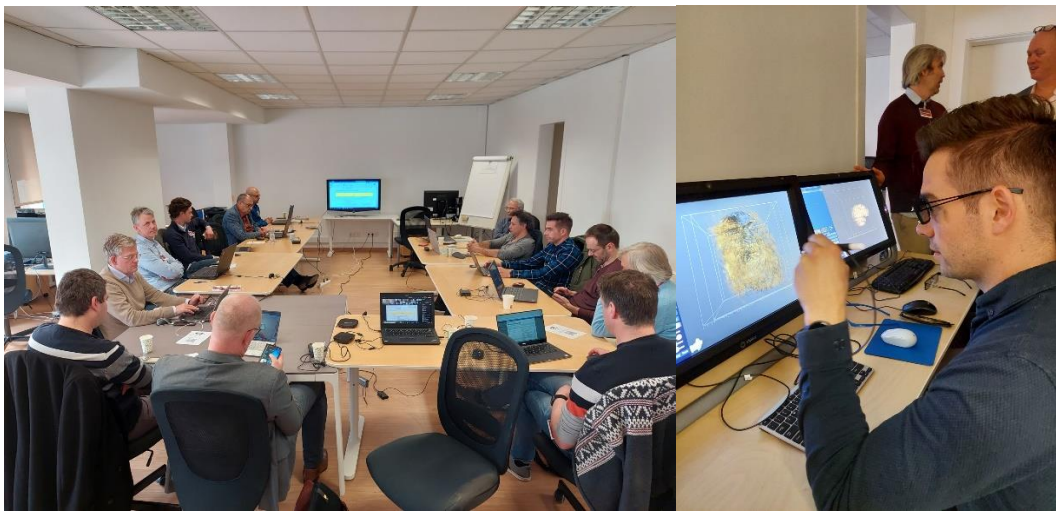

***Figure 2: Impression from first SIGNET General Assembly Meeting in Barcelona***

### 4.1.2 Information sharing

SIGNET consortium members use a file sharing and storage system to safely share project information, presentations and even photos. A link is given on the public website. Access is shielded by a user code and password. The user-friendly file transfer environment is structured around Documents (frozen) and Workspace (works in progress). The Documents section

[3] Due to COVID-19 pandemic, face-to-face meetings may be replaced by online meetings
[4] Due to delays in national funding the first kick-off meeting was with an incomplete consortium.

contains o.a. the current project plan and approved deliverables. Within the Workspace section different work packages (WPs) each have their own space.

### 4.1.3 Workshops

In addition to the general assemblies smaller workshops have been and will be held on either National level, use cases or specific topics.

### 4.1.4 Other Tools

Other internal communication tools include mailing lists (participant, WP and at the consortium levels), internal staff meeting and meeting minutes, web conferencing etc.

## 4.2 External dissemination tools

External dissemination designates actions aiming at ensuring the visibility and awareness of the results outside the Consortium borders, i.e., in the scientific community, in academic institutions, in other research organizations, or among the lay public. These tools include:

### 4.2.1 Project Public Information Sharing

A LinkedIn page is setup to spread awareness and engagement about SIGNET in the professional community.

Link to the SIGNET LinkedIn page:
https://www.linkedin.com/company/itea-signet

In addition to the LinkedIn page, a public website is being prepared to presents general project information, participant information, downloadable publications and deliverables.

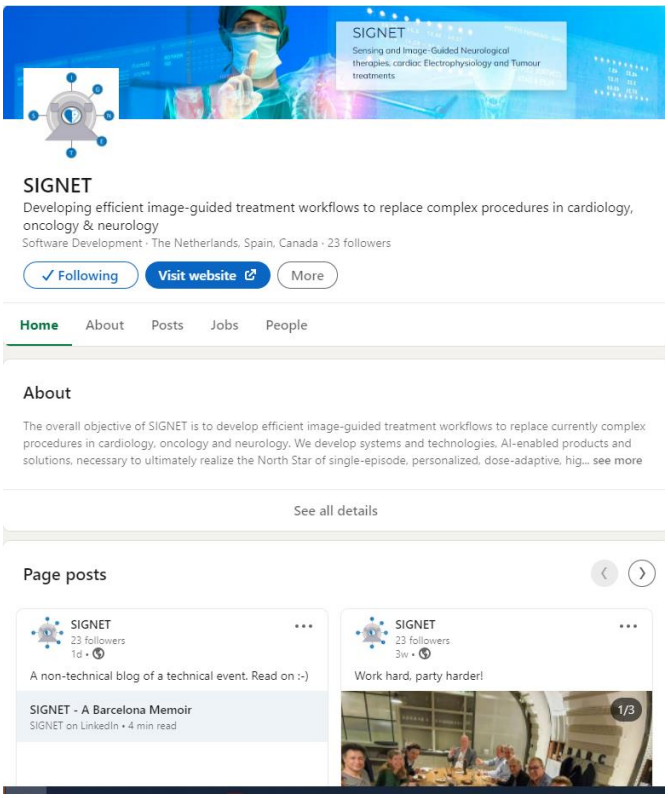


***Figure 3: SIGNET LinkedIn page***

## 4.2.2 Publications and presentations

SIGNET project results will be submitted for publication in scientific journals, conferences, and workshops. The submission of papers jointly written by project participants is encouraged.

Given the diversity of use cases and tools being addressed in SIGNET, a wide variety of national and international journals, conferences and workshops can be targeted to disseminate SIGNET results. The selection of a certain dissemination platforms will, apart from the topic, also depend on the timing. Not all conferences are held every year, and also the timing within the year may vary.

Journals targeted by SIGNET include:

**Medical Science Journals**:

- Physics in Medicine and Biology / Medical Physics
- Magnetic Resonance in Medicine
- International Journal of Hyperthermia
- Journal of Magnetic Resonance Imaging (JMRI)
- Physics and Imaging in Radiation Oncology (phiRO)
- Human Brain Mapping
- Journal of Neuroscience
- Journal of Neuroimaging
- NeuroImage
- Brain Stimulation
- Cancer Imaging Journal
- The Journal of Neurosurgery
- Radiotherapy & Oncology

- International Journal of Radiation Oncology Biology and Physics

**Technology/engineering journals:**

- IEEE Transactions on Medical Imaging, on Pattern Analysis and Machine Intelligence and on Computerized Medical Imaging and Graphics for image processing,
- IEEE Transactions on Visualisation and Computer Graphics, Computer and Graphics,
- IEEE Transactions on Image Processing, IEEE Transactions on Biomedical Engineering,
- IEEE Transactions on Information Technology in Biomedicine
- Elsevier's Medical Image Analysis

Conferences:

- International Society for Magnetic Resonnance in Medicine conference (ISMRM)
- American Society for Radiation Oncology (ASTRO)
- Radiology Society of North America (RSNA)
- European Society for Therapeutic Radiology and Oncology (ESTRO)
- Organization for Human Brain Mapping (OHBM) Conference
- Society for Neuroscience (SfN) Conference
- Medical Image Computing and Computer Assisted Interventions (MICCAI) Society
- International Society for Optics and Photonics (SPIE)
- American Association of Physicists in Medicine (AAPM)

### 4.2.3 Press releases and social media

Press releases will be organized on an ad hoc basis to disseminate special milestones and/or project results. Very often media coverage cannot be orchestrated but "happens" as a result related dissemination activities.

### 4.2.4 Alignment with other European Projects

SIGNET exploits the results of the ITEA3 projects SoRTS and STARLIT. Both projects have provided state-of-the-art technology to Philips MR scanners and allow the exploitation of real-time motion-correction. The innovations were targeted at MRI-guided radiation therapy mainly in collaboration with Elekta and a key component was a real-time, low-latency and bi-directional interface between the two systems. This concept of integrating diagnostic MRI scanners with a therapy device will be further expanded in SIGNET to develop the generalized COMRADE interface.

The Health-TKI project MIGRATE aimed for improving cardiac function by using active cell compounds instead of cells combined with smart biomaterials to fixate the cell compounds to their target. A complete MRI-guidance toolkit was developed to inject the cells at the right location in the heart. The visualization of these treatments is fundamental and a platform for MRI-guided therapy has been developed in MIGRATE to support these treatments. SIGNET will leverage this platform for the Cardiology use case.

### 4.2.5 Education and Innovation

Educating young scientists and involving them in innovation is an important aspect of the SIGNET project. SIGNET is actively involved in graduation assignments for M.Sc. and Ph.D. students which (partially) take place at industrial partner premises. In addition some industrial researchers have also an university position.

Several partners also employ company internal means to educate colleagues in the activities and results of the SIGNET project.

# 5. Standards Development strategy

## 5.1 Introduction

Market access for complex innovative system-of-systems like those developed in SIGNET requires compliance with EU MDR as well as 21 CFR in the US and other similar laws in China, Japan, Canada, Australia, etc. Demonstration of compliance often depends on using approaches from standards for adjacent system technologies, but may require development of new standards beyond the generic medical device standards (ISO 14971, IEC 60601-1, IEC 62304, IEC 62366, ISO21860 and others). SIGNET partners will contribute in its creation and relevant discussions.

Image guided intervention and cancer treatment are addressed by many groups and standardization bodies in Europe and globally, and thus after an initial phase of gap analysis and the identification of immediately applicable standards, activity in standardization will focus on building new standards wherever it is needed. The academic partners will leverage their existing networks in professional bodies, and extend their contacts, to ensure adoption of MR guided RT into appropriateness criteria and reimbursement schemes. This will be supported through industrial trade associations. An overview of the policy value chain is provided in Figure 4.

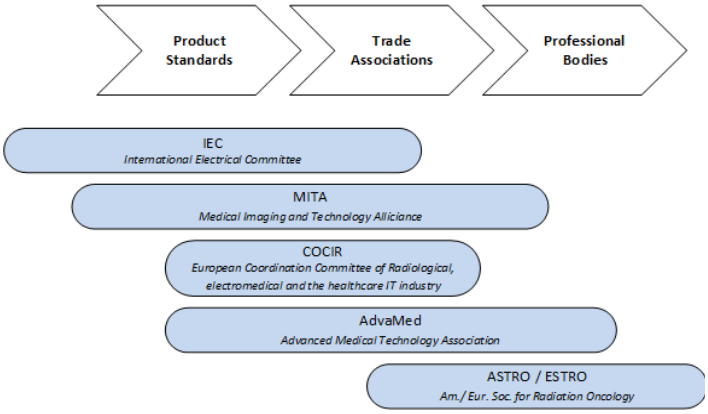


***Figure 4 : Policy Value Chain for Image Guided Interventions and Therapies***

## 5.2 Overview of applicable standards

SIGNET focuses on developments of medical equipment, and specifically those to be used in the vicinity of the Magnetic Resonance Imaging system. This comes with special requirements, related to the high magnetic field and its resulting attraction forces, as well as the harsh electromagnetic environment and the high sensitivity of the MR receivers.

Requirements for Basic Safety and Essential Performance of medical equipment is covered by IEC TC62 and three of its four sub-committees: SC 62A for general requirements (electrical, mechanical, EMC, software, alarms), SC 62B for imaging equipment (like MRI – for which the 4th edition was approved in June 2022), SC 62C for radiation therapy equipment, and SC 62D for other (therapeutic) equipment. Several of the therapeutic devices for which SIGNET researches innovations are not covered by 'particular standards' developed in SC 62D. These devices will need to rely on their own approaches to scientifically demonstrate that risk control measures are sufficient and adequate (no "presumed compliance" based on consensus standards).

Specific standards for assessing physical safety characteristics for MR systems are developed by MITA as NEMA standards, for RF exposures (Whole Body SAR) and for acoustics, and by ASTM for attraction, torque and heating of items brought near or into the MR system.

With the advent of AI/ML, many standards developments initiatives are on-going. Figure 5 provides an overview of the multiple organization active in this field. SIGNET partners will identify relevant standards to influence and to implement in the context of MR-guided therapy.

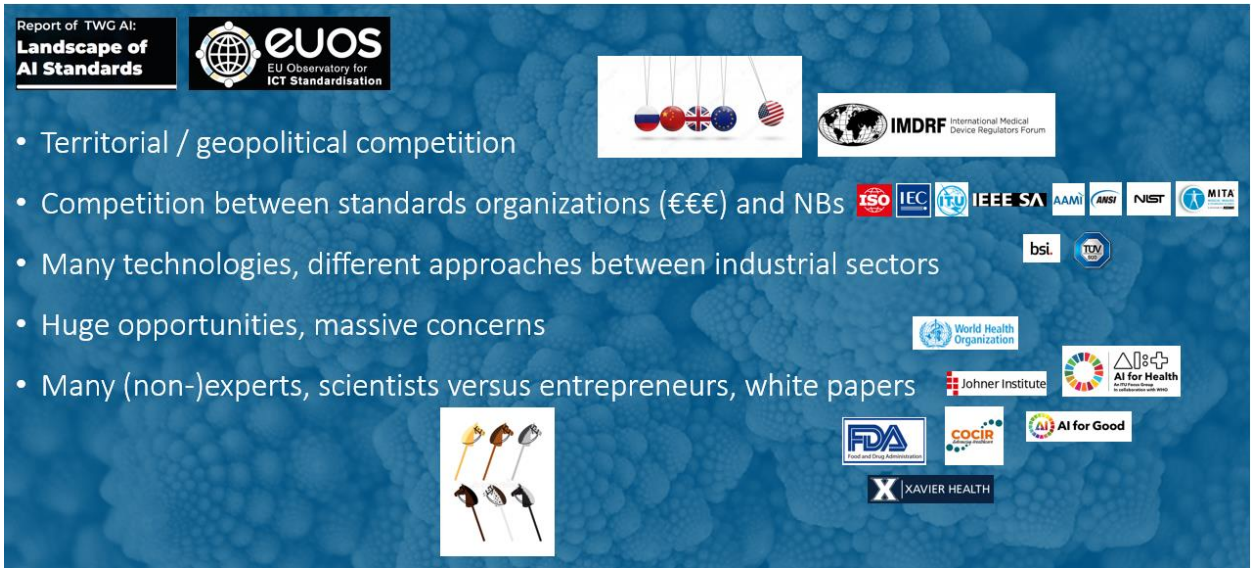


***Figure 5: Overview of Standards Development Organizations (SDOs).***

Many of these standards are so-called horizontal standards, which apply across industrial domains and applications. Vertical or domain-specific standards generally take precedence over horizontal standards. Irrespective, conflicting requirements may exist and careful review and alignment of these emerging standards and regulations (like the EU AI Act, the Medical Device Regulation, and the Machinery Regulation) are necessary. SIGNET partners, particularly Philips, is well connected to trade associations like COCIR to influence the European standards development landscape. Figure 6 provides an overview of the most important safety risk management and SW/AI/ML development process standards for medical devices versus horizontal standards.

Image guided therapy applications will include AI/ML capabilities in four different areas: (*i*) imaging (embedded AI or Software in a Medical Device, SiMD), (*ii*) safety & workflow oversight (including all Machinery requirements), (*iii)* Prediction Algorithms or Computer Aided Detection (Software as a Medical Device, SaMD), and (*iv*) system verification and monitoring (logging as a service, digital twinning). Figure 7 provides further details of the many AI/ML related standards in the different application areas, and horizontal standards. Notably, no standardization initiatives currently exist where it comes to diagnostic image quality using embedded AI/ML. SIGNET partners are developing functionality in this realm, and will consider if and when to propose a new work item to cover these capabilities.

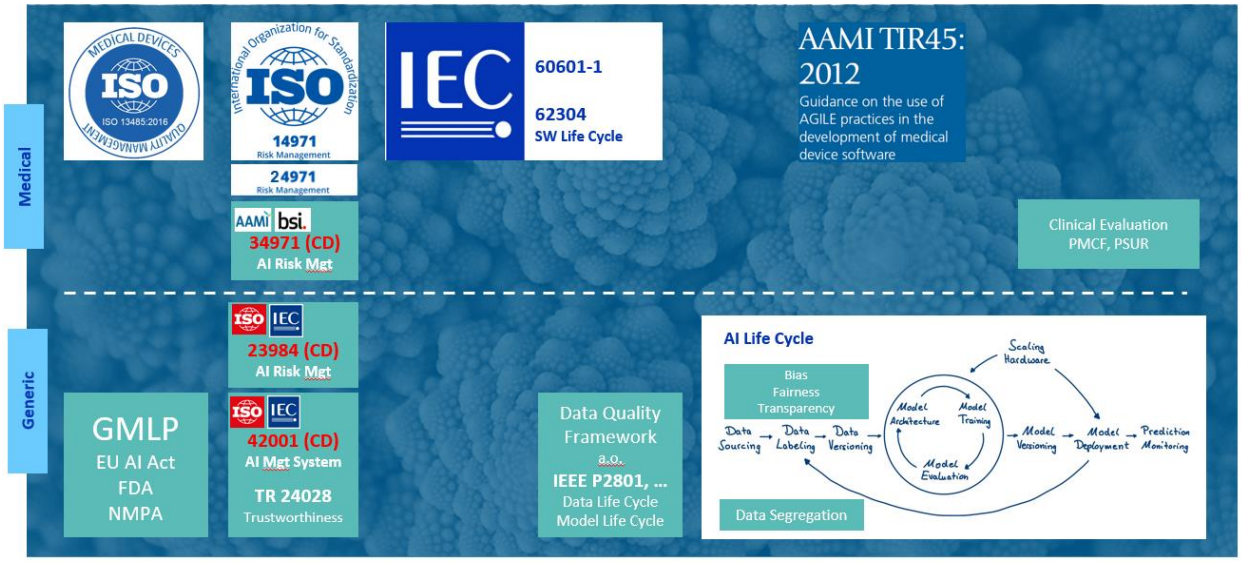


***Figure 6: Overview Medical Devices AI standardization initiatives, with focus on Quality Management Systems (QMS), Design Controls, Risk Management, Data Management.***

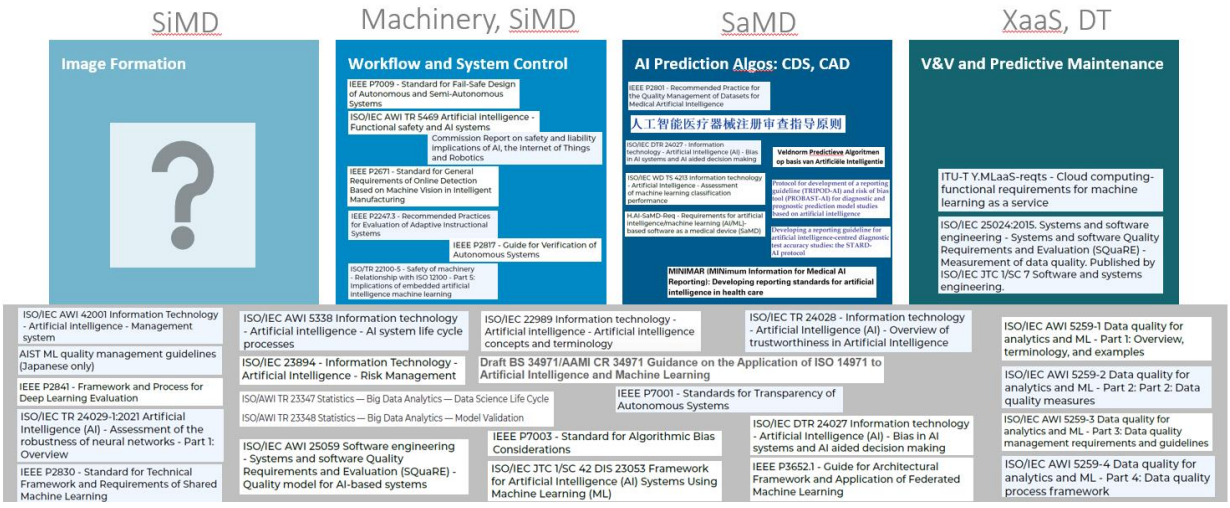


***Figure 7: Overview of the four pillars of technologies and applications leveraging AI/ML capabilities in Image Guided Therapy applications, and currently known standards.***

## 5.3 Engagement in SDOs

SIGNET partners, and especially Philips, is actively contributing to and influencing new and revised standards. At least the standards identified in the table below are being covered. Review and contributions to AI/ML standards will be conducted as new versions appear, through a.o. membership of the Dutch Standards Organization (NEN).

| Standard | Title |
|---|---|
| **IEC TR 60601-4-6** | Medical electrical equipment – Part 4-6: |

| | |
|---|---|
| **(PT 62A-1)** | Essential performance fault safety |
| **IEC 60601-2-33 Ed 4** | Medical electrical equipment – Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis |
| **NEMA MS4** | Acoustic noise measurement procedure for diagnostic magnetic resonance equipment |
| **ASTM F2503** | Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment |