Innovation Funnel for Valuable AI in Healthcare

Introduction

Researchers and developers increasingly create digital health applications such as apps, modules in the electronic patient record or other software based on AI and other algorithms or decision-making rules. Sometimes, a mismatch occurs between what is developed and what is required in practice, which can stand in the way of an application's successful implementation and added value for healthcare.

In order to help researchers and developers in the process from the development to the scale-up of valuable applications, this tool contains pointers regarding the legal and regulatory scope for action. This enables them to prepare early for minimum requirements or standards and to reflect on actions aimed at creating people-oriented, reliable applications. The Innovation Funnel for Valuable AI in Healthcare supports this innovation process in five domains: value, application, ethics, technology and responsibility. Integrating these in an innovation funnel helps create maximum value: each phase offers space to work in creative and iterative ways, while at the same time having a well-defined goal within the process and being supported by the substantiated commitment of funds. Each phase transition (gate) includes a checklist that helps ask the right questions at the right time. When all of the gate's requirements have been met, the process can move on to the next phase in the innovation funnel. In this way, the innovation complies with all laws, regulations and user expectations as it is being developed.

Publication details

This MVP was developed by an action team, part of the Valuable AI for Health programme of the Ministry of Health, Welfare and Sport. It is a first step towards a community-based tool to be developed.

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Phases

Idea
Generate and collect ideas that add value to health and healthcare.

Exploration
Explore required resources, underlying questions and possible solutions and combine these to create a conceptual design.

Development
Collect required resources and develop a testable solution (MVP).

Pilot A
Validate the solution without patients.

Pilot B
Test the solution with patients.

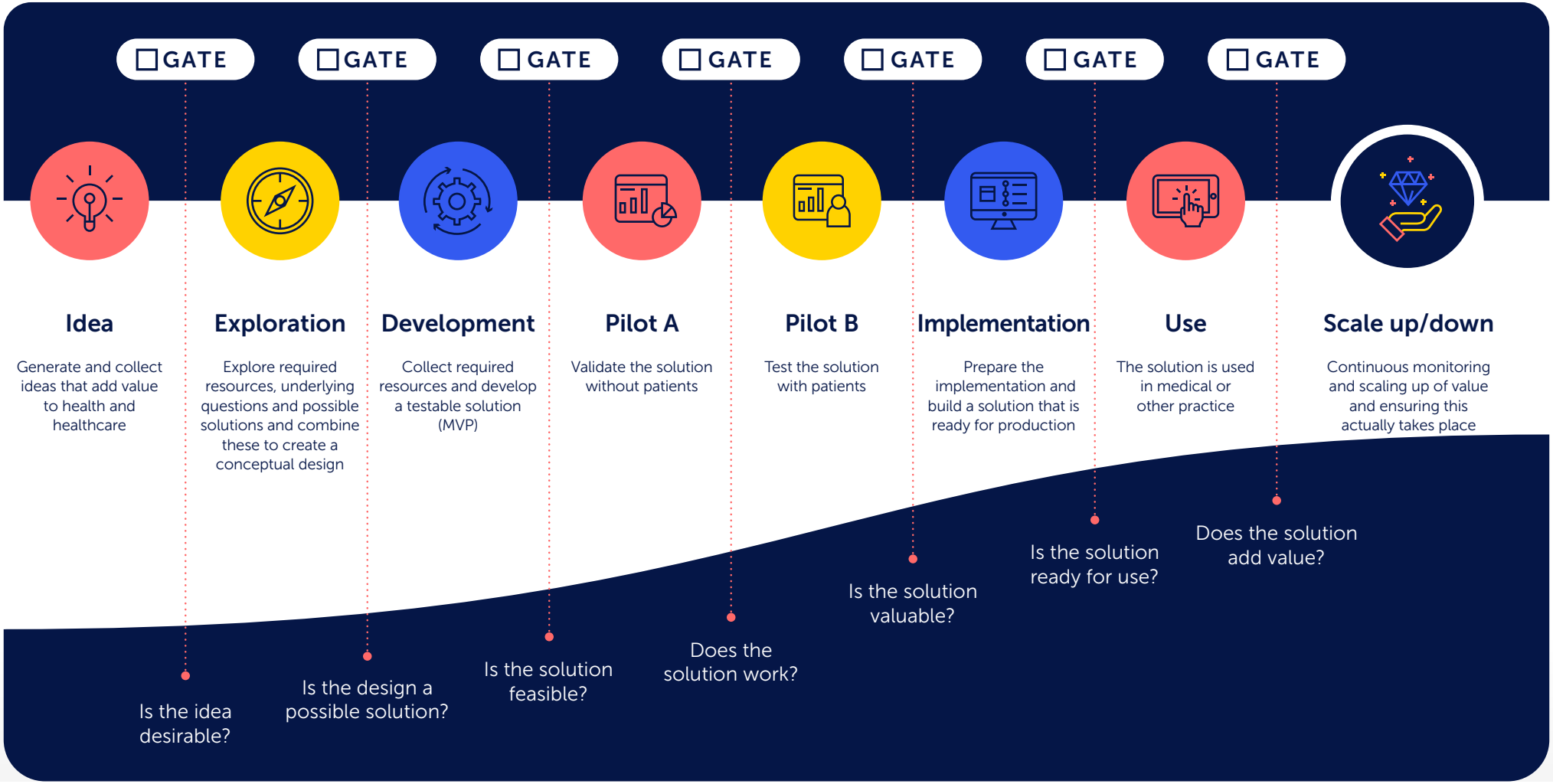
Implementation
Prepare the implementation and build a solution that is ready for production.

Use
The solution is used in medical or other practice.

Scale up/down
Continuous monitoring and scaling up of value and ensuring this actually takes place.

AI tool

New project | Existing project



Gate 1 – Finalising the Ideas Phase

Is the idea desirable?

The words in boldface express the core of each requirement.
See the glossary for an explanation of relevant concepts.

Value

- ☐ A clear **situation, complication and question** (SCQ) are described: to what question does the idea provide a solution, and is it better or less invasive than **alternative** (technical or non-technical) **solutions**?
- ☐ It has been determined who the intended **end users** (including patients) are, and the idea's tangible value has been described from their perspective.
- ☐ Potential **stakeholders** have been identified, and an impact analysis has been carried out in broad strokes, defining positive and negative consequences (medical, economic, social).
- ☐ The solution's final outcome (**life cycle**) has been decided on:
  - Internal use or scale-up (regional, national, international)
  - Funding source
- ☐ There is a broad outline (pitch) for a social or other **business case** for development and implementation, indicating where costs and benefits will occur and how the idea contributes to obviating, shifting and replacing healthcare

Application

- ☐ **Personas** for the intended end user or users (including patients) have been defined in order to study in-depth who they are, including characteristics and perceptions.
- ☐ A process exploration has been carried out, analysing the current workflow (**status quo**).

Technology

- ☐ It has been determined whether enough **data** will be available for a reliable solution and where the data need to come from (including who is responsible for them).
- ☐ It has been decided on the basis of an impact analysis (of costs, knowledge, infrastructure) whether the required technology and data will be **purchased or developed** in-house and/or together with partners.

Accountability

- ☐ The governance with roles and **responsibilities** required for implementing the idea has been identified, including an active **strategic ambassador** for creating support.
- ☐ The feasibility and **conditions** for responsible use have been discussed and assessed with **experts** in the fields of privacy, information security, ethics, legal affairs and/or medical legislation.
- ☐ An initial **risk scan** for the use of the application has been carried out; risk areas and issues that require an in-depth risk analysis (such as PRI, FMEA or CIA) have been identified
- ☐ An initial **DPIA** has been carried out for the exploration phase, with purpose limitation and a principle that fits the context (such as scientific research or quality improvement in healthcare) for data processing and the requirements this gives rise to, such as consent. Explicit attention is paid to privacy risks and appropriate measures (e.g., only coded data, data minimisation).

Do not forget to save changes as you go along!

Gate 1 – Finalising the Ideas Phase

Is the idea desirable?

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- ☐ **Contractual arrangements** on data protection and IP are in place for data processing by external partners.

Ethics

- ☐ A **broad impact analysis** at the level of society and of medical and other health practice has been carried out, and the proportionality of benefits versus risks has been determined.
- ☐ The impact on **inequalities** in practice and their desirability has been assessed.
- ☐ It has been analysed to what extent the application can add useful information to medical practice. This includes looking at the **end user's ability** (skills, role/position and context) to interpret the intended outcomes correctly and convert these into valuable actions.
- ☐ It has been specified how the idea can have a positive influence on the central organisational goals and the three important underlying values (see **Begeleidingsethiek**).

Gate 2 - Finalising the Exploration

Is the design a possible solution?

The words in boldface express the core of each requirement.
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Value

- ☐ The client has determined the definitive **research question**, scope and potential for a scale-up.
- ☐ **User stories** have been described: I [as an end user] want [functionality] for [intended goal/added value].
- ☐ A complete **stakeholder analysis** has been carried out, with costs and benefits described for all stakeholders and a description from their perspective of the solution's desirability and feasibility and of what is required to adopt it.
- ☐ A valorisation strategy has been created to **redeem** and **scale up** the solution's value (external suppliers, intellectual property, involvement of TTP).
- ☐ The **business case** for developing and testing the solution has been carried out and takes into account (1) the obligations of the manufacturer of medical technology and (2) the expected risk classification of the intended application. The required funds and means are available.
- ☐ A **market scan** of financial and other partners and competitors has been carried out: potential partners have been involved for the follow-up, and **alternative** solutions from competitors are being monitored.

Application

- ☐ A **client/patient journey** has been described to obtain insight into how end users in the workflow interact with the solution. Any required modifications to the work process have been elaborated.
- ☐ A **prototype** solution has been developed to understand the product format and associated user and designer requirements and to understand how the product meets the standards required of it.

Technology

- ☐ A **data end report** has been produced that includes:
  - descriptive data analyses;
  - reliability and quality of data;
  - a data dictionary with data definitions;
  - validation by domain experts of decisions regarding data supply or processing.
- ☐ An **start architecture** has been created that makes it clear what infrastructure is needed to make the application available safely and reliably (e.g., NEN7510 and 'privacy by design').
- ☐ A **development plan** has been written setting out how the algorithm will be developed, what design decisions were made and what acceptance criteria there are for its performance.

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Gate 2 - Finalising the Exploration

Is the design a possible solution?

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Accountability

- ☐ A **liability analysis** has been carried out together with the client, experts and suppliers: which legal requirements must the application meet, and how will this be taken into account?
- ☐ It has been determined whether the application is a **medical device** and, if it is, to what risk class it has been assigned, provisionally or otherwise. The possible certification or self-certification process and its consequences (costs, time) have been determined.
- ☐ The risk scan has been expanded to include a **risk management plan** that defines acceptance criteria for the application's foreseeable risks. An initial **risk-benefit analysis** has been carried out, with a positive outcome.
- ☐ The DPIA has been updated for data processing in the development phase, and the objective has been refined. Non-essential data have been removed from the data set (**data minimisation**), and the data to be used have been aggregated where possible (**subsidiarity**).
- ☐ It has been determined who the **manufacturer** is. Optionally, it has also been determined with a legal adviser that the manufacturer meets all applicable legal requirements (e.g., a certified quality system such as ISO13485/ISO15189), also if the solution will only be used internally by the legal entity in question and/or in case of self-certification
- ☐ A draft **clinical evaluation plan** (depending on the risk class) has been drawn up, defining how appropriate evidence for clinical performance will be gathered on the basis of clinical association, technical performance and clinical validation. The plan has been assessed by an independent or other expert.
- ☐ A specific risk classification has been drawn up regarding **information security** (in accordance with CIA, for instance), and the development phase infrastructure complies with this classification.

Ethics

- ☐ The design is subject to **ethics by design**: 1) there are courses of action at the level of technology, behaviour and environment to guarantee ethical use (see ethics of supervision) and 2) the legitimacy of these options is tested openly.
- ☐ There is proof of **consent and autonomy** on the part of patients, with visible measures in place to safeguard their wishes.
- ☐ The required support has been explored by determining the impact on the daily life of end users, stakeholders and the system and by determining the required knowledge and skills for an **acceptable human interaction** with the solution.

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Gate 3 - Finalising the Development

Is the solution feasible?

The words in boldface express the core of each requirement.
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Value

- ☐ The **developed application** and choice of model have been recalibrated using:
  - the originally defined value for **end users** and/or **stakeholders**;
  - the **added value** compared with the existing situation or with alternative solutions;
- ☐ the application or minimum viable application has been demonstrated using **demos** in the course of development and has been discussed with the **client**, existing or potential **partners** and **funders** for the pilot/implementation phase.
- ☐ Using the demos, the **business case** has been refined for the follow-up phases.

Application

- ☐ **Personas**, character profiles and scenarios for the use of applications have been documented.
- ☐ **Expert sessions** with healthcare providers and patients have been organised for the pilot phases. **Ambassadors** for implementation have been identified and involved early on.
- ☐ The application meets the design requirements for **user experience** (UX) and standards for **user interaction** (UI) and the corporate identity.
- ☐ **Training** and schooling for users involved in pilot A are ready for use.

Technology

- ☐ **Data collection** and storage have been provided for, including a data model and a repository for recording data definitions that facilitate **interoperability** – e.g. healthcare information building blocks (e.g., ZIBs, FHIR).
- ☐ The definitive **architecture map** for data storage/processing and computing infrastructure is available, and the server space has been determined, including security certificates.
- ☐ The **definitive algorithm** has been determined and meets the acceptance criteria for the performance. The design documentation (functional, technical) has been delivered, including explicit attention for bias (desired/undesired), data drift and human intervention.
- ☐ A **functional application or minimum viable application** is ready for use in pilot A.

Accountability

- ☐ A **definitive risk class** has been determined for a medical device, with corresponding requirements for clinical evaluation. In case of a purchased product, it has been determined whether the intended application falls within the **intended use** as described by the manufacturer.
- ☐ It has been determined positively whether CE certification is required and, if so, how this requirement is being met. A specific plan has been drawn up for the **certification process**, and any required document templates have been requested from a notified body.

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Gate 3 - Finalising the Development

Is the solution feasible?

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- ☐ The **risk management plan** has been updated: risks have been addressed (elimination, containment through control measures, acceptance), and residual risks have been described. A new **risk-benefit analysis** has been carried out and has had a positive outcome.

- ☐ The **DPIA** has been updated for pilot phase A, and the objective has been refined. Data are coded or encrypted whenever possible. When data are processed **outside of the institution** and/or outside of the European Economic Area, there are contractual agreements on data protection.

- ☐ A **clinical evaluation report** has been written with a reasoned clinical association on the basis of a literature review and research from the development phase. There is a plan for pilot A to further substantiate the technical performance.

- ☐ A specific risk classification has been drawn up for **information security** (in accordance with CIA, for instance), and the infrastructure for pilot A complies with this classification.

- ☐ A draft **Investigational Medical Device Dossier (IMDD)** has been compiled consisting of documents in CCMO (Central Committee on Research Involving Human Subjects) format:
  - C1: description of the problem, application and risk classification;
  - C2: agreements on the manufacturer and production;
  - C3: design documentation and acceptance criteria;
  - C5: risk management plan (including a risk-benefit analysis);
  - C6: clinical evaluation report;
  - Appendix: privacy and security reports.

Ethics

- ☐ An analysis has been carried out to verify whether the application's current structure fits the **norms and values** of the specific medical or other practice in which it will be playing a role.

- ☐ The application duly respects and supports the user's **autonomy**: it allows for greater freedom or freedom of choice and a better insight into the user's own decisions and values.

- ☐ A due diligence check has been done for:
  - the right **level of transparency** for the end user and required modifications;
  - the approach to **sensitivity and the permitted use** of data in terms of storage and processing;
  - fairness of the error margin in outcomes and the way **errors** are addressed in medical or other practice.

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Gate 4 - Concluding Pilot A

Does the solution work?

The words in boldface express the core of each requirement.
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Value

- ☐ The expected **added value** (risk-benefit analysis) has been evaluated and optimised (sensitivity versus specificity) on the basis of the pilot results.
- ☐ The tested application has been demonstrated using **demos** in the course of development and has been discussed with the **client**, existing or potential **partners** and **funders** for the pilot/ implementation phase.
- ☐ Through the demos, **financial resources** have been made available for pilot B.
- ☐ The **business case** has been refined on the basis of the pilot results. A **validation plan** is ready to provide insight into and measure the application's quantitative and qualitative added value/costs in practice (pilot B) as well as the health gains.

Application

- ☐ An **incentives analysis** has been carried out for the use of technology and its validation in pilot B:
  - Performance expectancy: how much does it benefit the end user?
  - Effort expectancy: how much effort does it require from the end user?
  - Social Influence: which peers stimulate the end user?
  - Facilitating conditions: which conditions facilitate the use?
- ☐ There have been **expert sessions** with users in the pilot, and feedback has been processed and provided to healthcare providers, patients/patient associations and ambassadors. Expert sessions for the next pilot phase have been organised.
- ☐ The **user interaction** (UI) has been evaluated with the users in the pilot and meets standards for the visually impaired and people with low literacy skills.
- ☐ **Training** and schooling for users involved in pilot B are ready for use. Expectations and rules on handling data and outcomes are described in terms and conditions and in the operational instructions.

Technology

- ☐ The definitive **data storage** is available in the environment that will be used in pilot B.
- ☐ A scalable **development environment** has been designed in accordance with DTAP, creating connections with existing infrastructure and presorting in accordance with the existing enterprise architecture.
- ☐ The **definitive application** has been developed in accordance with applicable standards (such as NEN62304) and is available in the development environment. The application meets the acceptance criteria for minimum performance. If the algorithm has been modified, return to Gate 3.

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Gate 4 - Concluding Pilot A

Does the solution work?

The words in boldface express the core of each requirement.
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Accountability

- ☐ The **governance** and **agreements** with external suppliers and partners are in place for pilot B (roles and responsibilities, security, supply, conditions, confidentiality and liability) and guarantee the safe and reliable use of the application.
- ☐ The **risk management plan** has been updated based on the results of pilot A. A new risk-benefit analysis has been carried out with a positive outcome.
- ☐ The **DPIA** has been updated for data use in the **context of research** in pilot B, and the objective has been refined. Purpose limitation and the legal principle for processing have been determined (such as scientific research with the corresponding requirements for or derogation from consent). Attention has been paid to data minimisation, subsidiarity and possible data processing outside of the European Economic Area.
- ☐ Based on pilot A, the **clinical evaluation report** has been updated to include the **technical performance** (performance, explicability, reliability of outcomes including representativeness of the patient population and possible data drift). A plan is in place for pilot B to carry out clinical validation.
- ☐ A specific risk classification has been defined for **information security** in pilot B, with safeguards that apply to this classification with regard to the required security levels and security (e.g., data breaches, hacking): logging, two-factor authentication, access control, no direct access to the data, backups and encryption.
- ☐ A definitive IMDD has been drawn up and assessed:
  - Medical-Scientific Research with People Act (WMO) research: approval from the Medical Research Ethics Committee **(MREC)**;
  - non-WMO research evaluation by an independent party (e.g., a data protection officer/medical technology department).
- ☐ A definitive **privacy statement** is in place for use in pilot B.

Ethics

- ☐ A **validation list** of expected consequences of using the application in pilot B has been drawn up for evaluation in medical or other practice.
- ☐ The social and societal **impact analysis** has been recalibrated based on the results up to and including pilot A.
- ☐ A list of **stop criteria** has been drawn up for pilot B for monitoring and mitigating harmful or undesired effects. Rescue procedures or rescue medication are available.
- ☐ **Informed consent** for the use of data and of the application has been obtained before the start of pilot B.
- ☐ Any undesired functionalities (**function creep**) have been considered and compared to the functionality as initially conceived (intended use).

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Gate 5 - Concluding Pilot B

Is the solution valuable?

The words in boldface express the core of each requirement.
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Value

- ☐ The client has determined the application's **added value** for end users and stakeholders and has weighed this against the original expectation, current practice and alternative solutions.
- ☐ The application works, fits in with medical or other health practice and has been **accepted** by the client on the basis of user experiences.
- ☐ A new check has been carried out for relevant **stakeholders** in the value chain for implementation in practice. New stakeholders have been informed of the application's scope and of follow-up steps.
- ☐ A projection of options for **scaling up** has been discussed with the client, existing or potential partners and funders. The level of implementation (internal or also external) has been decided on.
- ☐ The quantitative and qualitative costs/benefits have been **measured** in pilot B, and the **business case** has been refined on the basis of this evidence. Optionally, the business case has been made part of an early Health Tech Assessment (**HTA**) for a broader economic evaluation of the added value to the healthcare system.

Application

- ☐ Operational and social **effects of use** of the application for people and processes have been weighed. The client/patient journey has been validated with the end user. Associated personas and process flows have been updated.
- ☐ **Expert sessions** have taken place with users in the pilot; feedback has been processed and analysed for implementation actions. Feedback has been given to healthcare providers, patients/patient associations and ambassadors.
- ☐ The **user experience** (UX) and **user interaction** (UI) have been measured, analysed and documented. The learning curve for end users has been found not to be too steep.
- ☐ The **training needs** per type of end user have been determined, and training materials are clear and ready for use.
- ☐ It has been determined on the basis of the pilot experiences which **changes** of **protocol**, management and policy are required.

Technology

- ☐ The definitive **data storage** is available in the production environment. Interoperability is guaranteed (e.g., through **data standards**). If the application has been modified, return to Gate 3.

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Gate 5 - Concluding Pilot B

Is the solution valuable?

The words in boldface express the core of each requirement.
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Accountability

- ☐ The definitive **risk-benefit analysis** has been determined, including the clinical evaluation report and the acceptance of residual risks.
- ☐ The **DPIA** has been updated for data use in a **training context** in the implementation phase. Purpose limitation and the legal principle for processing have been determined (as well as any requirements for consent). Attention has been paid to data minimisation, subsidiarity and possible data processing outside of the European Economic Area.
- ☐ The IMDD has been converted into a **product dossier** in accordance with instructions and formats of the notified body or the manufacturer for risk class I/self-certification.
- ☐ The **clinical evaluation report** has been updated to include the clinical association, the technical performance and the **clinical evaluation**. It has been determined that the application is safe and effective for its intended use.
- ☐ A specific risk classification has been defined for **information security** for training purposes in the implementation phase, with safeguards that apply to this classification with regard to the required security levels and security (e.g. data breaches, hacking): logging, two-factor authentication, access control, no direct access to the data, backups and encryption.

Ethics

- ☐ An analysis of proportionality has been carried out with regard to the **burden** for stakeholders, in particular as regards risks, work pressure and emotional burden.
- ☐ It has been assessed what the effects will be on the **treatment relationship** between healthcare provider and patient, weighing the variation in experiences, in particular the experience of illness and responsibility within **validity** in the healthcare process.
- ☐ The broader **scientific** of the application has been assessed and is considered to be sufficient.
- ☐ Undesired functionality (**function creep**) has been identified on the basis of pilot B, and mitigating measures have been taken.

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Gate 6 - Finalising the Implementation Phase

Is the solution ready for use?

The words in boldface express the core of each requirement.
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Value

- ☐ A public description and justification of **utility and need** is available in view of implementation partners and **society** (social returns).
- ☐ A check has been carried out to determine that, in the practical environment, the application functions as observed in pilot B: **functionalities** for **end users** have not been changed.
- ☐ **Stakeholders** in the value chain for implementation have been involved, and there is a consensus about the distribution of costs/investments and benefits/gains in the value chain (see eHealth values model).
- ☐ **Funding agreements** are in place for the structural funding of implementation and scale-up. Agreements have been made with the client, funders and partners to make the applicable **conditions for approval in practice** concrete.
- ☐ There is a definitive version of the **business case**. A measuring and **monitoring system** has been arranged to measure costs and benefits in practice.

Application

- ☐ An **implementation plan** per type of target group (including type of end user and level of digital capacities) is ready for roll-out.
- ☐ **Information and promotion** (including promotion materials) are available regarding the appropriate use, interaction and context of the application (Healthcare Quality, Complaints and Disputes Act (Wkkgz); Medical Treatment Contracts Act (WGBO); assessment framework 3.4.1) for patients and healthcare providers. A media campaign is ready for roll-out.
- ☐ The application **meets** functional and other **standards**, certifications and the corporate identity.
- ☐ End users have completed final **acceptance tests** (functional and non-functional requirements).
- ☐ All end users are **trained** and able to work with the application (usability check). Functional **manuals** and training materials are available for parties involved in the management and use of the application.
- ☐ **Procedures** and governance **for safe use** (compliant with the covenant on the safe use of medical or other technology) are in place and clear to all those involved. **Functional management** and support are available.

Technology

- ☐ The definitive application has been integrated into the data or other **architecture**, validated (including certifications) and stress-tested (including computing power). The application can be undone/removed, and there is a **kill switch** in case of emergencies (with a back-up method).
- ☐ **Technical management** and support are available. There is a maintenance and audit plan with technical manuals, training materials, an impact analysis in case of changes, testing requirements and an update/upgrade process (including for obsolete equipment).

Do not forget to save changes as you go along!

Gate 6 - Finalising the Implementation Phase

Is the solution ready for use?

The words in boldface express the core of each requirement.
See the glossary for an explanation of relevant concepts.

Accountability

- ☐ The **governance** and **agreements** with external suppliers and partners are in place for production (roles and responsibilities, security, supply, conditions, confidentiality, data processing and liability) and guarantee the safe and reliable use of the application, both inside and outside of the European Economic Area.
- ☐ The application has been **released** for use on the market or for internal use. In case of approval for use on the market, the application bears a CE logo, has been registered in EUDAMED and has a UDI.
- ☐ The **risk management plan** has been updated to include a description of how the positive risk-benefit assessment is safeguarded during the production phase (indicators, monitoring residual risks, acceptance criteria for new and established risks).
- ☐ A new **DPIA** has been carried out for **production**. Purpose limitation and the legal principle for processing have been determined (for example, the Medical Treatment Contracts Act, quality improvement and/or scientific or other research with the applicable requirements for or derogation from consent), as have data minimisation and subsidiarity.
- ☐ **A post-market clinical follow-up plan** has been drawn up. Depending on the risk class, the clinical evaluation report needs periodic updating and assessing by an independent body using clinical data and end user experiences that are representative of practical experience.
- ☐ A specific risk classification has been defined for **information security** for production, with safeguards that apply to this classification with regard to the required security levels and security (e.g. data breaches, hacking): logging, two-factor authentication, access control, no direct access to the data, backups and encryption.
- ☐ A definitive **privacy statement** and **terms and conditions** are in place for use in the production phase.
- ☐ A **post-market surveillance plan** has been drawn up on the basis of the post-market clinical follow-up plan and the risk management plan.

Ethics

- ☐ Desired **bias** in the application has been assessed, and measures have been taken to prevent undesired bias, including clear communication towards end users.
- ☐ Clear **limits of use** of the application have been defined, including criteria for appropriate use by end users.
- ☐ **Unforeseen consequences** have been considered, and it has been determined whether and to what extent the application's use requires monitoring. Stakeholders' **responsibilities** for correct use are clear. An evaluation method is in place for the practical phase.

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Gate 7 - Continuous Value Assessment

Does the solution add value?

The words in boldface express the core of each requirement.
See the glossary for an explanation of relevant concepts.

Value

- ☐ There is continuous **monitoring** of whether the application's expected **added value** and impact remain proportionally positive compared to alternative solutions.
- ☐ A continuous check is in place to ensure the application functions in the practical environment as it did in pilot B: in case of changes to **functionalities** for **end users**, the added value is reconsidered.
- ☐ A continuous impact analysis is in place to monitor the application's positive and negative consequences (medical, economic, social) for **stakeholders**.
- ☐ A plan for regional, national or international **scale-up** has been formulated and, together with partners and funders, implemented.
- ☐ The **business case** for scaling up has been determined. A Health Tech Assessment (HTA) has been carried out to determine the incremental cost-effectiveness of entry to the insured market.

Application

- ☐ The development and implementation process has been evaluated with the actors involved, and **lessons learned** have been identified for the roll-out of subsequent versions.
- ☐ A continuous **test and evaluation cycle** is in place to check and improve functionality, user experience and interaction, and appropriate use (add to the PMS plan).
- ☐ Functional **manuals** and training materials have been **updated** following the implementation of new versions of the application.
- ☐ There is a p**lan for transitioning to the new work practice** by adopting the application: old work processes are scaled down or moved (in collaboration with partners and funders).

Technology

- ☐ There is a technical plan for **scaling up** the application using:
  - the route (app stores or through own organisation);
  - a recalibration of the data or other architecture plan;
  - a recalibration of the design (functional and technical, including a test of older systems).
- ☐ Technical **manuals, documentation** and training materials have been updated following the implementation of new versions of the application.

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Gate 7 - Continuous Value Assessment

Does the solution add value?

The words in boldface express the core of each requirement.
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Accountability

- ☐ The **post-market surveillance plan** is carried out in case of external use:
  - reporting about incidents and field safety corrective actions (at the Health and Youth Care Inspectorate (IGJ)) through PMCF reports;
  - reporting significant technical changes and, if needed, updating the CE file (for instance, in case of changes to the algorithm and intended use) and the risk-benefit ratio on behalf of the notified body.
- ☐ Implementation of the quality and risk management processes and continuous **evaluation** of the experience with the **clinical use** of the resources in case of internal use, including corrective actions.
- ☐ In case of changes to the data processing (new principle, new person responsible, new cooperation partner, new manufacturer, etc.), a new **DPIA** is carried out.
- ☐ There is a periodic recalibration of the risk classification for **information security** in the production phase.

Ethics

- ☐ There is a continuous check of the level of **trust** (both the physician's and the patient's) in medical interventions that use the application, and improvement measures are carried out.
- ☐ There is a continuous evaluation of the **effect on the care relationship** with regard to automation bias and loss of essential skills (deskilling) among end users for the provision of quality care.
- ☐ Continuous identification of **undesired bias** takes place in the user process to ensure that healthcare continues to be provided equitably to the entire user group.
- ☐ A re-evaluation is in place for specifically identified circumstances in which the **limits of use** are exceeded.
- ☐ There is continuous monitoring of possible **future difficulties**:
  - The aspects for monitoring have been evaluated.
  - It has been decided when interventions are needed.
  - It has been decided who is responsible for the application's functioning and who will take action in case it malfunctions.

Do not forget to save changes as you go along!

Organisation and support

The Innovation Funnel for Valuable AI in Healthcare is intended for multidisciplinary development and implementation, with a focus on creating value in practice. This means that various parties are involved from the outset to increase the chance of success.

Multidisciplinary development team from the start

On the basis of an initial brainstorming session, assemble a multidisciplinary core team that includes at least a developer/researcher and an end user. Preferably, this end user should also be responsible for the content of the project as a 'product owner' and is an ambassador for adoption in medical or other practice. This could be either a healthcare provider or a patient (or citizen), but ideally both are involved on the principle of joint decision-making. The core team may be supplemented with a project leader. In addition, it is advisable at an early stage to engage expertise in the domains described in the tool, such as data management, ethics, valorisation, legal affairs, change management and privacy and to involve any cooperation partners.

Demos and support

Transparency in the process helps test for value, progress and opportunities for cooperation. Ideally, the project team should get together in scrum sessions to discuss progress and demonstrate intermediate results. Preferably, these demos should involve interested parties and partners external to the team so as to create support and collect feedback. The considerations and decisions are recorded clearly, and the decision to approve the phase transition is discussed in the team, with the final decision made by the product owner.

Working with the tool allows a client to obtain a rapid, structured overview at the management level of the progress of projects taking place in the organisation. The phase transitions and their go/no-go criteria can be used to prioritise projects.

Glossary

Acceptance criteria	Criteria set by the organisation that must be met to take the product into use.
Ethics of supervision	Methodology for guiding the ethical use of technology by formulating courses of action in the design phase at the level of people, the environment and technology.
Bias	A prejudice or distortion in the algorithm that has negative consequences for certain groups and/or individuals.
CIA	Confidentiality, Integrity and Availability. A risk classification methodology that organisations can use to design their information security measures.
CCMO	Central Committee on Research Involving Human Subjects.
CE certification	Mandatory marking that shows a service or product meets the requirements that apply within the European Economic Area.
Covenant for the safe application of medical devices in hospitals *(Convenant Veilige Toepassing van Medische Technologie in de Medisch Specialistische Zorg).*	The covenant's aim is to ensure the safe use of medical devices in specialised medical care. Its core concept is: 'a safe medical device in the hands of a competent user in a healthcare setting that can guarantee safe use'. A medical device is specially intended for diagnostic or therapeutic purposes and can be: a medical apparatus, medical software, a consumable, a reusable, an implant or an in-vitro diagnostic device.
Data-dictionary	A detailed, uniform description of all names, definitions, attributes and relationships in the data.
Data drift	Unexpected, documented changes over time to the data distribution, data structure, data definitions and data infrastructure, which can lead to distorted and inexplicable outcomes of the AI algorithm.
Data minimisation	Legal obligation when collecting and processing personal data not to use more data than are needed for achieving the objective.
DPIA	Data Protection Impact Assessment. An instrument for the advance identification of the privacy risks of processing certain data, so appropriate risk-reducing measures can be taken.
Encryption	Encryption of sensitive data.
Ethics by design	Principle where ethics are taken into consideration from the start of the development process and throughout the product's life cycle, and where the most ethically preferred option is the default.
EUDAMED	European Database on Medical Devices – European database that will (over time) include data on all medical devices and their manufacturers. Manufacturers must include the data required by the MDR in EUDAMED; among other data, this includes data about the device, the clinical research, the CE certification and reports regarding PMS and vigilance. EUDAMED is partially public and will be released for use gradually in the coming years.

Glossary

FHIR	Fast Healthcare Interoperability Resources Standard for exchanging digital data within and among healthcare institutions.
FMEA	Failure Mode and Effects Analysis.
Health Tech Assesment (HTA)	A systematic evaluation of the direct/indirect and intended/unintended effects of healthcare technology in order to determine its impact.
Principle	The legal term for a good reason/objective for the processing of personal data. The General Data Protection Regulation (GDPR) describes six principles as legitimate reasons. Have low-threshold consultations with a data protection officer about a legitimate principle. A more detailed explanation of these principles, and information on the requirements for them, is available from the website of the Dutch Data Protection Authority: Are you allowed to process personal data? | Dutch Data Protection Authority.
IGJ	Health and Youth Care Inspectorate.
IMDD	The Investigational Medical Device Dossier specifies the contents of the documentation on medical devices (still lacking CE marking) in clinical research to be submitted to the review committee (MREC or CCMO).
Informed Consent	Procedure according to which patients/citizens are informed and provide active consent for the use of their data and the use of an application.
ISO standard	A standard issued by the International Organization for Standardization, the organisation that publishes international standards.
IVDR	In Vitro Diagnostic Regulation. The European legislation that supervises the use of medical devices for in-vitro diagnostics, which will enter into force on 26 May 2022.
Client/patient journey	Methodology for a cohesive description of all phases and interactions of the healthcare process that patients go through, from the perspective of patients.
Clinical evaluation	The analysis of available clinical data from the literature or from one's own clinical research with the goal of substantiating the safety and effectiveness of a medical device.
Quality management system	The entirety of coordinated, documented work processes for safeguarding the quality of a process, e.g. ISO 13485, ISO 15189.
Life cycle	The life cycle of medical devices, as described in the Covenant for the safe application of medical devices in hospitals, consists of three phases: introduction, use and rejection.
Logging	The systematic logging of the use and experience of a software application, allowing for any errors, erroneous use or illegitimate access to be traced and accounted for.

Glossary

MDR	Medical Device Regulation – European legislation regarding the use of medical devices, which entered into force on 26 May 2021.
Medical device	The MDR (Article 2) defines 'medical device'. The core of this definition is: each instrument, unit or apparatus, piece of software, implant, reagent, material or other article intended by the manufacturer for separate or combined human use for one or more medical purposes as described in the MDR.
MREC	Medical Research Ethics Committee (*Medisch Ethische Toetsingscommissie*).
Minimum Viable Product (MVP)	An initial version of a product or service that is made available to end users as early as possible in order to collect feedback on the principle of 'fail fast and cheap'.
NEN standards	Standards issued by the NEN that cover the Dutch agreements on the quality and safety of products, services and processes.
Notified body	A government-appointed body that assesses whether medical devices with an average or high risk meet legal standards to be allowed onto the European market. When a medical device is commercially available, the notified body also carries out periodic checks of the manufacturer.
DTAP	Acronym for Development, Testing, Acceptance and Production. This is used to describe the sequential steps in software development and implementation.
Personas	A detailed and realistic description of a user/stakeholder of your product or service.
Post-Market Clinical Follow-up (PMCF)	The active collection of data on clinical experiences with a medical device after its admission to the market.
Post Market Surveillance (PMS)	A collection of activities the manufacturer needs to carry out to monitor the safety and performance of its product once it is on the market. It consists roughly of two parts: clinical evaluation and risk management.
PRI	Prospective Risk Inventory.
Privacy by design	Principle where privacy is taken into consideration from the start of the development process and throughout the product's life cycle and where the most privacy-friendly choice is the default.
Privacy statement	Informational message to patients and end users about the processing of personal data.
Profiling	A process in which personal data are processed to demonstrate a connection between characteristics of individuals and their behaviour in order to predict behaviour.
Residual risk	Risks that persist in spite of all measures taken.

Glossary

Risk class	Medical devices are categorised in four risk classes on the basis of the risks of their use by patients. The lowest risk class is subdivided into four subcategories. The classification of medical devices has been tightened under the MDR (which entered into force on 26 May 2021), causing significant consequences for software, among other consequences.
Risk-benefit analysis	Weighing an application's risks and benefits so as to decide on its legitimacy.
Risk-benefit ratio	The application's risk-benefit ratio that is used to determine its legitimacy.
SCQ	Methodology for structuring information to form a clear message that sets out the situation, the complication and the question.
Subsidiarity	The requirement to use the least invasive means to achieve a certain goal. For the purposes of data processing, this usually means using as few traceable data as possible.
TTP	A Third Trusted Party (TTP) is an independent party responsible for exchanging, connecting and encrypting privacy-sensitive data.
Two-factor authentication	Multiple access control to verify a user's authenticity.
UI	User interface (UI) stands for the valuable user environment one tries to achieve with one's application (the product's look and feel).
Unique Device Identification	A worldwide, harmonised system of unique codes for identifying medical devices. The MDR prescribes a UDI for every medical device after a transition period.
Usability check	Methodology for analysing and validating the application's usefulness.
User Stories	A short, simple description of a need of an end user, always structured as follows: As a [*end user's role*], I want [*desired insight, functionality*] in order to [*action perspective, goal*].
UX	User experience (UX) stands for the valuable user experience one tries to achieve with one's application (the interaction with and experience of the product).
Medical Treatment Contracts Act (WGBO)	The Medical Treatment Contracts Act (WGBO) sets out the rights and duties of patients undergoing a medical treatment. This includes the right to privacy and the confidentiality of medical data, as well as the right to correction of errors in one's medical record.
Subject to the WMO	Research that is covered by the Medical Research Involving Human Subjects Act (WMO) must meet all requirements specified by the WMO. This is evaluated in advance by a qualified METC or CCMO.
ZIBs	Healthcare information building blocks (*Zorginformatiebouwstenen*). Methodology for making content-specific and functional agreements for standardising information in the healthcare process.

Reading list

General legal and other frameworks

MDR	https://www.rijksoverheid.nl/onderwerpen/medische-hulpmiddelen/nieuwe-wetgeving-medische-hulpmiddelen
IVDR	
Convenant	https://www.igj.nl/zorgsectoren/medische-technologie/toezicht-op-veilig-gebruik/convenant
IGJ Toetsingskader 'Inzet van e-health door zorgaanbieders'	https://www.igj.nl/publicaties/toetsingskaders/2019/10/18/toetsingskader-inzet-van-e-health-door-zorgaanbieders
AVG	Algemene verordening gegevensbescherming (AVG) | Autoriteit Persoonsgegevens
Avg handig	Inhoudsopgaaf EU algemene verordening gegevensbescherming (EU-AVG). Privacy/Privazy according to plan. (privacy-regulation.eu)
Uavg	wetten.nl - Regeling - Uitvoeringswet Algemene verordening gegevensbescherming - BWBR0040940 (overheid.nl)
Artikel 458 Wgbo (art 7:458 BW)	Voorwaarden gebruik medische gegevens voor wetenschappelijk onderzoek (autoriteitpersoonsgegevens.nl)
WMO	wetten.nl - Regeling - Wet medisch-wetenschappelijk onderzoek met mensen - BWBR0009408 (overheid.nl)
VWS: Hand-out wettelijke en normatieve kaders rondom AI in de zorg	Hand-out wettelijke en normatieve kaders rondom AI in de zorg | Publicatie | Data voor gezondheid
VWS: Handreiking AVG en AI	Handreiking AVG en AI | Publicatie | Data voor gezondheid
COREON statement hergebruik van patiëntgegevens voor wetenschappelijk onderzoek in het kader van AVG	https://elsi.health-ri.nl/categorieen/gegevensbescherming/mogen-patientgegevens-hergebruikt-worden-voor-wetenschappelijk

Technology and responsibility

CCMO format IMDD	https://www.ccmo.nl/onderzoekers/klinisch-onderzoek-naar-medische-hulpmiddelen/standaardonderzoeksdossier-medische-hulpmiddelen/d-productinformatie/d2-investigational-medical-device-dossier-imdd
MDCG Guidance 2019-11, Qualification and classification of software - Regulation (EU) 2017/745 and Regulation (EU) 2017/746	https://ec.europa.eu/health/md_sector/new_regulations/guidance_en
MDCG guidance 2019-16, Guidance on cybersecurity for medical devices	

Reading list

MDCG guidance 2020-1, Guidance on clinical evaluation (MDR) / Performance evaluation (IVDR) of medical device software	
Infographic, Is your software a Medical Device?	
Leidraad MDR: Review of a clinical investigation with a medical device – guidance document for MRECs	https://www.ccmo.nl/publicaties/publicaties/2021/05/17/leidraad-mdr-review-of-a-clinical-investigation-with-a-medical-device-%E2%80%93-guidance-document-for-mrecs
NEN-en-ISO-13485:2016 Medische hulpmiddelen - Kwaliteitsmanagementsystemen	https://www.nen.nl/en/nen-en-iso-13485-2016-c11-2017-nl-231912
NEN-en-ISO-15189 Medische laboratoria - Bijzondere eisen voor kwaliteit en competentie	https://www.nen.nl/en/nen-en-iso-15189-2012-c11-2015-nl-203486
NEN-en-IEC 62304 Software voor medische hulpmiddelen	https://www.nen.nl/en/nen-en-iec-62304-2006-en-fr-137115
NEN-en-ISO-14971 Toepassing van risicomanagement voor medische hulpmiddlen	https://www.nen.nl/en/nen-en-iso-14971-2019-en-266511
NEN7510 Informatiebeveiling in de zorg	Informatiebeveiliging in de zorg - ICT in de zorg - Zorg & Welzijn (nen.nl)
NEN7512 Gegevensuitwisseling	
NEN7513 Logging	
ISO/IEC27001 Informatiebeveiliging voor IT-bedrijven	
NFU Startdocument	https://www.nvz-kennisnet.nl/groep/100-mdr-ivdr
NFU Handvat Software als Medisch Hulpmiddel	
NFU Handvat In-huis ontwikkeling	

Reading list

NFU Handvat Klinisch Onderzoek	
NFU Handvat Zorginstelling als fabrikant	
Enisa rapport AI CYBERSECURITY CHALLENGES	Artificial Intelligence Cybersecurity Challenges — ENISA (europa.eu)
Vormgeven Post-Market Surveillance voor medische hulpmiddelen onder de MDR en de IVDR	https://www.fme.nl/system/files/publicaties/2021-02/PMS%20document.pdf
MDR Guide for Medical Software	https://www.fme.nl/mdr-guide-medical-device-software
Praktijkgids Medische Informatietechnologie	https://mtintegraal.nl/specials/1/speciale-uitgave-praktijkgids-medische-informatietechnologie
Medtech Europe MDR en IVDR trainingsmateriaal	https://www.medtecheurope.org/new-medical-technology-regulations/training-and-education/
Medtech Europe MDR Flowchart	https://www.medtecheurope.org/wp-content/uploads/2018/01/EN_MTE_MDR_Flowchart_Dec2017.pdf
BSI White paper: Recent advance-ments in AI – implications for medical device technology and certification	
BSI Whitepaper: Machine learning AI in Medical Devices: adapting regulatory frameworks and standards to ensure safety and performance	https://compliancenavigator.bsigroup.com/en/community/insight-page/?utm_source=pardot&utm_medium=email&utm_campaign=SM-SUB-LG-CN-CONTENT-2006
BSI Whitepaper: Post Market Surveillance – Requirements	
BSI Whitepaper: Effective post-market surveillance	
BSI Whitepaper: Software as a medical device	
BSI: MDR Documentation Submissions, Best Practices Guidelines	https://www.bsigroup.com/globalassets/meddev/localfiles/en-us/brochures/bsi-md-mdr-best-practice-guidelines.pdf

Reading list

Rapporteerrichtlijnen voor predictie-modellen voor individuele prognose/ diagnoses (TRIPOD)	https://www.bmj.com/content/350/bmj.g7594
Richtlijnen voor protocollen voor klinische studies met AI (SPIRIT-AI)	https://www.nature.com/articles/s41591-020-1037-7
Rapporteerrichtijnlijnen voor klinische studies met AI (CONSORT-AI)	https://www.nature.com/articles/s41591-020-1034-x
Een BIAS assessment tool voor studies met predictiemodellen (PROBAST)	https://www.acpjournals.org/doi/10.7326/M18-1376

Ethics

Handleiding aanpak begeleidingsethiek	Handleiding aanpak begeleidingsethiek voor artificiële intelligentie (AI) in gezondheid en zorg | Nieuwsbericht | Data voor gezondheid
Toolbox voor Ethisch Verantwoorde Innovatie (Digitale Overheid)	Toolbox voor Ethisch Verantwoorde Innovatie (digitaleoverheid.nl)
Tool DEDA: De Ethische Data Assistent	Utrecht Data School | De Ethische Data Assistent (DEDA)
Whitepaper Algemene Rekenkamer: Aandacht voor algoritmes	Aandacht voor algoritmes | Rapport | Algemene Rekenkamer
Whitepaper SIDNfonds: AI will see you now	Rapport "AI will see you now" - verantwoord gebruik AI ter ondersteuning van medische beslissingen | Rapport | Data voor gezondheid
Guidelines European Commission: Ethics guidelines for trusworthy AI	Ethics guidelines for trustworthy AI | Shaping Europe's digital future (europa.eu)
Ethisch parallel onderzoek ondernemen	https://bmcmedethics.biomedcentral.com/articles/10.1186/s12910-020-00524-z
Ethics by design approach (in de AI context)	https://arxiv.org/pdf/2010.07610.pdf
Ethische omgang met problematische bias in medische AI	https://www.sciencedirect.com/science/article/pii/S0933365720312306
Verantwoord gebruik van big data in de medische context	https://www.jmir.org/2019/3/e11732/

Reading list

Betrokkenheid patienten faciliteren in AI study design (basis informed consent)	https://www.bmj.com/content/bmj/368/bmj.l6927.full.pdf
Vertaling AI tool naar klinische praktijk en de grenzen van AI daarbinnen	https://link.springer.com/article/10.1186/s12916-019-1426-2

Value/Impact

Whitepaper ECP: Artificial Intelligence Impact Assessment	ECP | Artificial Intelligence Impact Assessment
Tool NL AI Coalitie: AI-Routekaart	AI-Routekaart (ai-routekaart.nl)
Whitepaper Erasmus MC: eHealth waardenmodel	https://www.eur.nl/eshpm/media/89013

Application

Whitepaper UXPA Magazine: The Fourth Lens: Making Design Thinking Work for Digital Health User Experience	The Fourth Lens: Making Design Thinking Work for Digital Health User Experience Magazine (uxpamagazine.org)

Other relevant reports, guidelines and tools regarding the application of AI in healthcare can be found at www.datavoorgezondheid.nl