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CAIDX

CAIDX TOOL #1

CLINICAL AI PATHWAY GUIDE

For clinicians with a clinical need, where an AI tool might be the solution and companies to get an understanding of the steps necessary for successful implementation

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The Clinical AI Pathway Guide

GOA 2.2

What is The Clinical AI Pathway Guide?

Wondering how to successfully navigate the complex path of AI development in healthcare?
The Clinical AI Pathway Guide is a practical and structured guide designed specifically to support healthcare practitioners in the development and implementation of **AI solutions**.

It offers a clear, stage-based framework to help healthcare teams move from early ideas to real-world clinical use. The guide consists of **six stages**, each outlining key **actions** and identifying relevant **stakeholders** essential to AI development.

Why Use This Guide?

- **Structured Clarity:** Follow a clear, structured guide from concept to clinical deployment.
- **Maturity Tracking**: Use the TRLs in the guide to evaluate and communicate the maturity of your AI solution.
- **Stakeholder Alignment:** The guide helps you to identify who should be involved and when, fostering collaboration and accountability.
- **Clinical Relevance**: Through the guide you will engage with tasks that will help you ensure, that your AI development stays grounded in real-world healthcare needs and practices.
- **Risk Reduction:** The guide will help you to address ethical, technical, and regulatory factors early-avoiding surprises later.

What are TRLs?

A central feature of the guide is the use of Technology Readiness Levels (TRLs) to assess AI solution maturity, track progress, and ensure readiness at each step.
The TRLs measurement system ranges from TRL 1 (lowest), where the basic principles are observed, to TRL 9 (highest), where the technology is proven in a operational environment and integrated in clinical practice.

See more: TRLs

The Clinical AI Process Model

Although the guide is structured in stages from 1-6, AI development is rarely linear. This iterative process model visualizes the real need for moving back and forth between stages—allowing for continuous learning, refinement, and better alignment with clinical, technical, and regulatory demands.

As a complement to the guide, the model underscores the importance of a post-market monitoring phase, even after the AI solution has been deployed and integrated into the clinical setting.

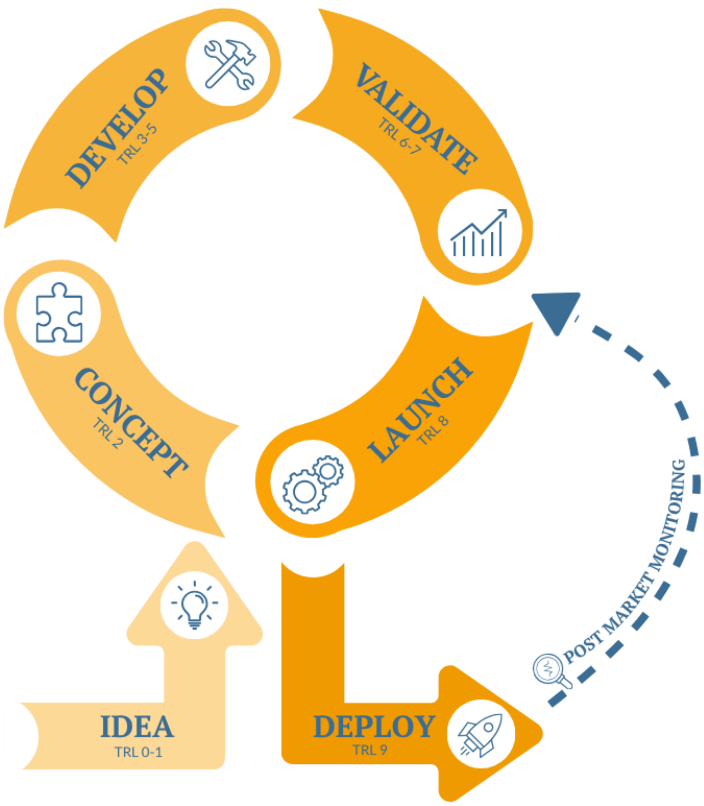

***Figure**: The Clinical AI Process Model*

Ready to Begin?

The following sections will provide structured guidance to support a thorough and effective engagement with the guide.

1. IDEA - From Idea to Basic Principle

Introduction

When you get an idea for a new AI healthcare solution, it is essential to begin with a clear vision and well-defined strategy to ensure the solution is both relevant and effective. This includes defining the clinical need, gathering stakeholder insights, and getting an overview of ethical, regulatory, and practical requirements to guide the project. Early planning focused on market positioning*, funding, and team expertise ensures a structured approach, paving the way for a solution that is impactful, compliant, and aligned with real healthcare needs.

Outcome

The outcome will be a well-scoped AI project rooted in a real clinical need, shaped through stakeholder input and close collaboration between clinical, technical, and domain experts. Key ethical, legal, regulatory, and market factors will be identified early, creating a strong and strategic foundation for development.

OBS: Terms marked with * are defined in the glossary at the end of this document.

The Problem, the Need, and the Idea

Primary Stakeholders:

- Clinician

Secondary Stakeholders:

- Project Manager
- Data Engineer
- Company

Actions:

- Start defining the clinical problem you aim to solve with your AI solution.
- Start defining the expected value creation of your AI solution: Will it save time for the clinicians/end-users? Is it cost-effective?
- Start defining the current state-of-art to be used as baseline for comparison at a later stage.

- Start defining relevant clinical data needed for algorithm development: training and validation.
  - Have you involved clinicians in the process?
  - The data set should represent the targeted population
- Initiate dialogue with stakeholders or interested parties and AI competent developers/technical expertise in early phase.
- Make a stakeholder analysis.
  - Who are the different stakeholders? Who is important to include?
  - Examples could be:
    - Clinicians, patients, Data Engineers, UX designers, anthropologists, researches, IT architects and security experts, legal experts,d management.
- Consider doing a SWOT-analysis* on the current state-of-art.
  - What are the Strengths, Weaknesses, Opportunities and Threats?

Available Internal Material:

- Initiation

Available External Material:

- Tools for development. A handbook for those engaged in development activity
- A method, visual tool, and resource library guiding the development from early stage idea to innovation on the market
- CIMIT Healthtech Innovation cycle
- The CIMIT Healthcare Innovation Cycle - HealthTech Deliverables Checklist
- Randomised controlled trials evaluating artificial intelligence in clinical practice: a scoping review

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Clinical Utility Impact

Up to 2 months

Primary Stakeholders:

- Clinician

Secondary Stakeholders:

- Project Manager
- Company

*Words marked with a star is defined in the Dictionary in the bottom of the document.

Actions:

- Start collecting feedback from other clinicians/end-users'. Do they also see the problem? If yes, do the find it an applicable solution to solve the problem?
  - **Note**: It can be challenging to create understanding amongst clinicians about the impact of an AI solution in an otherwise well-documented clinical field, which can make it difficult for a clinician to evaluate.
- Start defining the expected benefits of the new AI-solution compared with traditional Standard Operating Procedures (SOP)*.
  - Ensure they are measurable for evaluation after implementation.

Available Internal Material:

- Initiation

Available External Material:

- Clinical evaluation of AI for health

Ethical Assessment

Up to 2 months

Primary Stakeholders:

- Clinician

Secondary Stakeholders:

- Company
- Project Manager

Actions:

- Have you defined potential risks or implications for the intended AI solution?
  - Patients?
  - Clinicians?
  - Data?

*Words marked with a star is defined in the Dictionary in the bottom of the document.

Available Internal Material:

- Initiation

Available External Material:

- Building STANdards for data Diversity, INclusivity, & Generalisablity
- Patient and public involvement to build trust in artificial intelligence: a framework, tools and case studies
- Z-Inspection: A Process to Assess Trustworthy AI
- Ethics and governance of artificial intelligence for health
- Framework for implementation and review of AI in healthcare
- Framework for Risk Categorization and Corresponding Considerations
- Risks, limitations, safety and verification of medical AI systems

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Collect Your Team

Primary Stakeholders:

- Project Manager

Secondary Stakeholders:

- Clinician
- Company

Actions:

- Identify the competencies and knowledge that can strengthen your project.
    - It is important to build a diverse team with both technical experts and clinicians (like doctors, nurses, psychiatrists) who can connect the technical side with the real-world needs of the project, especially for AI in healthcare.
        - A diverse team enhances the ability to progress through various TRLs adapting to evolving needs throughout the development process.
    - Are there internal or external individuals or organizations necessary to ensure interdisciplinary teamwork?

    - Some of the typical competencies needed in AI-projects include:
        - Clinicians, patients, Data Engineers, UX designers, anthropologists, researchs, IT architects and security experts, legal experts, management.
- Define Project Owner, Project Lead and eventually describe a Governance Structure for the project.
- Integrating a solution into a Hospital's IT-environment can be a real challenge. To address this, working with Hospital's IT-Departments and companies should be a priority early in the development phase to identify compliance requirements.
- Define the roles and areas of responsibilities within the team to ensure alignment within the team.

Available Internal Material:

- Clinical AI Pathway Stakeholders

Does it Already Exist?

Primary Stakeholders:

- Project Manager

Secondary Stakeholders:

- Clinician
- Company

Actions:

- Have you considered the following:
    - Making a competitor map?
    - Who are the potential end-users and buyers*?
    - Making a market size analysis*?
    - Pricing/reimbursement?
    - What is the target market (EU and/or others)?
    - Is there something similar to your solution on platforms like PubMed*?
        - Preliminary Freedom To Operate (FTO)*.

Available Internal Material:

- Initiation

*Words marked with a star is defined in the Dictionary in the bottom of the document.

Budget and Resources

Primary Stakeholders:

- Project Manager

Secondary Stakeholders:

- Company
- Clinician

Actions:

- Prepare budget and resource plan, outline priorities for each development phase.
  - If applicable, define the cost for each potential external consultant.
- Identify potential funding sources.
  - Look into which national or international calls for funding that are open.
  - Who can write the funding application (internally)?
- **Note**: Making a budget and resource plan should at this stage be used as a guideline.

Available Internal Material:

- Initiation

Intellectual Property Rights (IPR)

Up to 2 months

Primary Stakeholders:

- Project Manager

Secondary Stakeholders:

- Company
- Clinician

Actions:

- Have you defined the ownership and rights of the AI solution?
  - If yes, have you formalized this in an agreement?
- Remember to contact the Tech Transfer Office (TTO)*.
- **Note**: Software is automatically protected by copyrights.

Available Internal Material:

- Initiation

Project Plan

Up to 1 week

Primary Stakeholders:

- Project Manager

Secondary Stakeholders:

- Company
- Clinician

Actions:

- Sum up all your considerations and decisions from the previous point in a project plan, where you have identified:
    - The needs and value creation
    - Purpose of the solution
    - Target audience
    - Impact or effect
    - Purchasing model.
- **Note:** At this stage your considerations should not yet be in a contractual form, but rather be used as an overview.

Available Internal Material:

- Initiation

Available External Material:

- Business Modsel Canvas
- AI Project Canvas
- The Financial, Operational, and Clinical Advantages of generalist Radiology AI

Intended use of you solution

Primary Stakeholders:

- Clinician

Secondary Stakeholders:

- Project Manager
- Regulatory Expert
- Company

Actions:

- Define intended use of you solution to qualify/classify your product both as concrete type of medical device and AI system.

Overview of Regulatory Requirements

Primary Stakeholders:

- Project Manager
- Company
- Regulatory Expert

Actions:

- Familiarize yourself with the Medical Device Regulation(MDR)* / In Vitro Diagnostics Regulation (IVDR) as well as EU AI Act* definitions, obligations and requirements, as central CE-mark* regulations relevant to your product, by using the source document or other guidelines (for example, various *ISO standards).
- Get the overview of applicable legislation for your product. Due to the variety of product features AI solutions in a medical context could be subject to different sets of laws.
  - **Note**: Compliance with the EU AI act*, Medical Device Regulation (MDR)*/In Vitro Diagnostics Regulation (IVDR) might not be enough.
- Familiarize with regulatory strategies in collaboration with a legal expert.

Available Internal Material:

- Initiation

Available External Material:

- COMPL-AI
- TÜV AI LAB Assessment Matrix
- The AI Act Explorer
- OpenRegulatory Templates
- Questionnaire „Artificial Intelligence (AI) in medical devices“
- Guideline for AI for medical products
- Key Terms for AI Governance
- Artificial Intelligence in Healthcare: Current Regulatory Landscape and Future Directions

*Words marked with a star is defined in the Dictionary in the bottom of the document.

Legal Collaboration Considerations

Primary Stakeholders:

- Legal Department
- Project Manager

Secondary Stakeholders:

- Clinician
- Company

Actions:

- Have you considered if you need to collaborate with external or private collaborators?
    - In that case, consider whether a formal collaboration agreement is necessary.

Available Internal Material:

- Initiation

2. CONCEPT - Conceptualization & Proof-of-Principle Development

Introduction

During Conceptualization & Proof-of-Principle* Development the focus is on refining the AI solution's design to meet clinical requirements and validating its feasibility. This involves defining user needs and technical specifications, creating an Algorithm development plan*, and deciding on key model parameters like accuracy, usability, and training type.

Ethical and regulatory preparations continue, with applications for data access, ethical approvals, and preliminary intellectual property assessments*. Early planning of data handling, anonymization of data, and quality standards further support compliant development. Strategic partnerships, an earning model, and regulatory alignment are also emphasized to ensure both functional and regulatory readiness as the solution takes shape.

Outcome

The outcome will be the necessary approvals secured to move forward, including data access and ethical clearances. With support from Senior Experts where needed, an Intellectual Property Rights (IPR) strategy and regulatory plan will be established, ensuring legal compliance and minimizing risks, setting the stage for the next phase of development.

End-user Requirements and Product Specifications

Up to 1 month

Primary Stakeholders:

- Clinician

Secondary Stakeholders:

- Company

Actions:

- Start defining requirements for usability, specificity and sensitivity of your solution with clinicians/end-users from other departments or hospitals.

Algorithm Development Plan

Up to 1 month

Primary Stakeholders:

- Data Engineer

Secondary Stakeholders:

- Clinician
- Project Manager
- Company

Actions:

- Consider inviting Senior Experts, research, Business Support Agencies as mentors or Advisory Boards to provide input and feedback on the strategy and/or required adjustments.
- Start deciding on required level of accuracy/verification plan*.

Available External Material:

- [Conceptual framework for a holistic AI literacy assessment matrix]

Applying for data

Primary Stakeholders:

- Clinician
- Company

Secondary Stakeholders:

- Legal Department

Actions:

- Possible data sources:
  - Patient data (hospital's data lakes*, biobanks, primary care, social care)
  - Available commercial data
  - Open-source data*.
- Assess the data for any potential technical quality issues.
- Note: approval processes can be slow. Contact your data provider early to obtain information regarding required documents, procedures, and expected timeline. You can also get support from the Hospital's IT-department and Data Engineers.
- Get acquainted with the legislation related to use of data for *Research & Development (R&D), EU level and national/ regional legislation.

- Clarify if patient consents are needed when data is collected or used for research and development.
    - Describe the process.

Available Internal Material:

- Initiation

Available External Material:

- Asking the right questions before using an artificial intelligence system
- The Data Protection Toolkit
- Self-assessment guide for artificial intelligence (AI) systems
- Secure Machine Learning Architecture (SEMLA)
- The METRIC-framework for assessing data quality for trustworthy AI in medicine
- Summary page from the EC around the EU AI Act

Intellectual Property Rights (IPR)

Up to 1 month

Primary Stakeholders:

- Project Manager

Secondary Stakeholders:

- Legal Department
- Clinician
- Company

Actions:

- Make a preliminary Intellectual Property Rights (IPR)* assessment.
- Set up the IPR strategy*.
- Reaching out to Tech Transfer Office (TTO)*.

Available Internal Material:

- Initiation

*Words marked with a star is defined in the Dictionary in the bottom of the document.

Regulatory Activities Across the Development Process

Up to 1 month

Primary Stakeholders:

- Company
- Regulatory Expert

Secondary Stakeholders:

- Legal Department

Actions:

- At this stage you should consider the requirements associated with a product and its development, as well as the general medical device manufacturer's obligations*. Your goal is to develop technical documentation which allows you to pass conformity assessment procedure successfully.
- Make a risk classification analysis according to Medical Device Regulations (MDR)*/In Vitro Diagnostic Regulations (IVDR) and the EU AI Act*.
- Make a GDPR risk assessment*.
- At this stage, have you considered the following:
    - Identified General Safety and Performance Requirements (GSPRs)* related to your product?
    - Appointed Person Responsible for Regulatory Compliance (PPRC)* within your institution?
    - Registered yourself as manufacturer of medical devices in European database on Medical Devices (EUDAMED)*?
    - Started to implement/adjust your Quality Management System (QMS)*?
        - Put emphasis on implementation of risk management and usability engineering concepts into your development work discipline.
- Define earning logic.
    - Are you going to make profit? If yes, how?
- Get in contact with your Notified Body*.

*Words marked with a star is defined in the Dictionary in the bottom of the document.

Available Internal Material:

- Initiation

Available External Material:

- List of Notified Bodies (NANDO)
- White Paper on the AI Act and its interactions with MDR / IVDR
- A Practical Guide to the EU AI Act for Internal Auditors
- TEAM-NB Position Paper: European Artificial Intelligence Act
- Exploring key stakeholders' perspectives on integrating the EU AI Act with the MDR for certifying AI medical devices

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Create Data Management Plan

Primary Stakeholders:

- Data Engineer
- Clinician

Secondary Stakeholders:

- Legal Department

Actions:

- According to your GDPR risk assessment identify whether your data needs to be anonymized, pseudonymized or other.
- **Note**: If in doubt, contact legal experts to be sure the data is handled correctly.

Available Internal Material:

- Initiation

Public-Private-Innovation Collaboration

Primary Stakeholders:

- Legal Department

Secondary Stakeholders:

- Project Manager
- Clinician
- Company

Actions:

- If external or private partners are needed, make a Public-Private-Innovation collaboration contract (PPI contract).
    - This should be clarified based on your reflections during the "Idea" phase.

Available Internal Material:

- Initiation

*Words marked with a star is defined in the Dictionary in the bottom of the document.

3. DEVELOP - From Proof-of-Concept to Prototype

Introduction

When transforming a conceptual AI model into a functional prototype, essential activities include gathering and preparing data, refining the algorithm, and selecting validation methods to ensure clinical accuracy. Emphasis is placed on regulatory compliance (e.g., GDPR*, EU AI Act*) and interdisciplinary collaboration. Additionally, clinical and cost-effectiveness analyses validate the model's applicability and impact in real-world settings.

Outcome

The outcome will be a functional prototype approved by your team, ready for retrospective validation using historical data. Preparations for prospective clinical testing will be in place, enabling real-time evaluation. These steps help verify performance, ensure clinical relevance, and mitigate risks ahead of implementation. This process ensures the prototype's readiness for safe and effective use, setting the stage for live testing.

Get Acquainted with the Legislation

Primary Stakeholders:

- Project Manager
- Clinician
- Company

Secondary Stakeholders:

- Legal Department

Actions:

- Remember to be aware of GDPR, Data Act* & EU AI Act* when developing the AI solution.
    - Consider contacting a legal expert if you are in doubt about legislation in certain areas.

Available External Material:

- GDPR
- Data Act
- EU AI Act

Receiving and Storing Data

Primary Stakeholders:

- Data Engineer

Secondary Stakeholders:

- Clinician

Actions:

- What is the status on receiving and storing the data that was defined in the "Concept" phase?
- Address your storage needs. How do you plan on storing (large) data files?

Available Internal Material:

- Initiation

Data Curation

Primary Stakeholders:

- Data Engineer

Secondary Stakeholders:

- Legal Department
- Clinician

Actions:

- Data preprocessing steps:
  - Get the Data dictionary*: what data do you have?
  - Do data sanity checks: automized plausibility checks of your data
  - Create statistics from the data to get an overview of your group of patients
  - Check the content of your data: do you have to update or transform it?

Revisit the Competencies in your Team

Primary Stakeholders:

- Project Manager
- Clinician

Secondary Stakeholders:

- Company

Actions:

- Do you need other types of competencies for the upcoming steps in the development?
- Are there internal or external individuals or organizations necessary to ensure *interdisciplinary teamwork?

Available External Material:

- [Artifcial intelligience tool development: what clinicians need to know]

Develop Algorithm

Primary Stakeholders:

- Data Engineer

Secondary Stakeholders:

- Company
- Clinician

Actions:

- Local validation is a critical step in AI algorithm development to ensure context-specific accuracy and reduce the risks associated with unvalidated commercial products. Therefore, it is important to:
    - Choose your validation methods
    - Retrospectively?
    - Statistics?
- Choose your software architecture.
    - Cloud vs. self-hosted?
- Using different types of data can help ensuring the robustness of the algorithm

*Words marked with a star is defined in the Dictionary in the bottom of the document.

- Make a plan for possible data bias.

Available Internal Material:

- Initiation

Available External Material:

- EU AI Act (article 8-15)
- Getting Ready for the EU AI Act in Healthcare. A Call for Sustainable AI Development and Deployment

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Verify your Model

Primary Stakeholders:

- Data Engineer
- Clinician

Secondary Stakeholders:

- Company

Actions:

- Determinate level of accuracy.
  - **Note**: Specificity and sensitivity is a clinical decision.
- Evaluation by experts and comparison with diagnoses determined using Gold-standard methods* can help determine whether the AI solution reliably detects what was intended and specified in the requirements analysis.

Available External Material:

- EU AI Act (article 8-15)
- Minimum Information about CLinical Artificial Intelligence Checklist for Generative Modeling Research (MI-CLAIM-GEN)
- Protocol for development of a reporting guideline (TRIPOD-AI) and risk of bias tool (PROBAST-AI) for diagnostic and prognostic prediction model studies based on artificial intelligence
- Checklist for Artificial Intelligence in Medical Imaging (CLAIM)
- DECIDE-AI: Reporting guideline for the early stage clinical evaluation of decision support systems driven by artificial intelligence
- APPRAISE-AI Tool for Quantitative Evaluation of AI Studies for Clinical Decision Support
- Unlocking the Value: Quantifying the Return on Investment of Hospital Artificial Intelligence
- SPIRIT 2025 explanation and elaboration: updated guideline for protocols of randomised trials

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Value Demonstration

Primary Stakeholders:

- Clinician

Secondary Stakeholders:

- Company
- Data Engineer

Actions:

- Clearly demonstrate the value of your AI solution. Highlight time savings for clinicians and cost-effectiveness, as these are critical factors in a clinic's decision to adopt your solution.

- Consider doing a Cost-Effectiveness Analysis*.
  - Do the benefits provided outweigh the costs of implementation/administration of the new test?
- What is the business/economic motivation for the implementation of your new tool?
  - Does the tool improve patient outcome, reduce costs, shorten/reduce hospitalization, improve selection of treatment, decreases morbidity and mortality?
  - Is this achieved without compromising patient outcomes?

- Revisit your definition of the intended use of the model under ""The problem, the need and the idea"" in the ""Idea" phase to reevaluate the potential of your AI solution as a new clinical care pathway.
- Consider where the new AI solution fits best:
  - New steps in Testing chain*?
  - Improves current steps?
  - Replaces current steps?
- Support from experts like Health Economic Specialist.

Prepare for obtaining Regulatory Approval

Primary Stakeholders:

- Company
- Regulatory Expert

Secondary Stakeholders:

- Legal Department
- Project Manager
- Data Engineer

Actions:

- At this stage, you should now have:
  - Obtained regulatory expertise as described in the ""Idea"" phase.
  - Familiarized yourself with the Medical Device Regulation (MDR)/In Vitro Diagnostics Regulation (IVDR)*, EU AI Act* definitions, obligations and requirements, central CE-mark* regulations as described in the ""Idea"" phase.
  - Developed technical documentation which allows you to pass conformity assessment procedure successfully as described in the ""concept"" phase.
- From here, you need to:
  - Start developing performance characteristics related to your medical device.
    - These attributes may include accuracy, precision, sensitivity, specificity, durability, and usability.
- Ensure your medical device is safe and performing for its intended use.

*Words marked with a star is defined in the Dictionary in the bottom of the document.

  - The most important dimensions are related with performance evaluation (scientific validity*, analytical performance* and clinical performance).
  - Document all the activities justifying your compliance with identified General Safety and Performance Requirements (GSPRs)*.
- You want to seek out a Medical Device Regulation (MDR)* experts for company-specific challenges on this topic.

Approvals for Prospective Testing

Primary Stakeholders:

- Legal Department
- Company
- Clinician

Actions:

- Get familiar with which approvals you need to perceive for the ""Validate"" phase to conduct a live test.
- Examples could be:
  - Internal organisational approvals
  - Approval from the ethics committee
  - Informed consent
  - Data and regulatory approval, clinical trial approval.

4. VALIDATE - of Technology Demonstrated in Operational Environment

Introduction

Validating the AI solution in clinical environments is done to ensure the prototype meets the clinical needs. This includes preparing for implementation by engaging users, refining market strategies, and collecting new data to verify performance. Clinical validation and regulatory tasks confirm that the solution meets safety, effectiveness, and regulatory standards. Documentation and transparency are prioritized to support a smooth path to regulatory approval, ensuring the solution is ready for deployment.

Outcome

The outcome will be a clinically validated AI solution tested in real-world settings to confirm safety, effectiveness, and alignment with clinical needs. A functional prototype/Minimum Viable Product (MVP)* with a user-ready interface will be developed to gather critical feedback for refinement. Validation data and documentation will support regulatory submissions, including Medical Device Regulation (MDR)* compliance, while commercial and technical implementation plans are refined. These actions position the solution for final approval and readiness for launch and deployment.

Collect Validation Data

Up to 1 year

Primary Stakeholders:

- Clinician
- Company
- Data Engineer

*Words marked with a star is defined in the Dictionary in the bottom of the document.

Actions:

- The validation data set cannot be the same as the training set. Therefore, you need new data set(s) and ethical approval for validation purposes.
    - Due to a new test involving potential new data, renewed approval is required for data use in compliance with GDPR and data access procedures.

Available Internal Material:

- Initiation

Conduct Clinical Validation

1+ year

Primary Stakeholders:

- Clinician
- Company
- Data Engineer

Actions:

- When conduction clinical validation you differentiate between internal and external validation:
    - Internal validation: The model is tested on data from the same source as it was trained on, to assess performance in a familiar setting.
    - External validation: The model is tested on data from a different source, to evaluate how well it generalises to new, unseen environments.
- Key assay parameters* established and defined (specificity, sensitivity, precision, etc.).
- Proof-of-Concept* report completed with assessment of clinical significance.
- It is a requirement cf. the EU AI Act* to ensure transparency in the results during the clinical validation.
    - Make sure that these results can be presented and reproduced.

Available External Material:

- Clinician checklist for assessing suitability of machine learning applications in healthcare
- Assessment of Radiology Artificial Intelligence Software: A Validation and Evaluation Framework
- CONSORT 2025 statement: updated guideline for reporting randomized trials

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Ensure Model Quality

1+ year

Primary Stakeholders:

- Clinician
- Data Engineer

Actions:

- Have you compared the model's capability on training data vs testing data to understand overfitting/underfitting?
- Is there enough training data to train the model?
- Have you required data amounts for building a quality model*?
- Analyze test/validation samples that are problematic to the model (e.g. high loss or wrong result with high confidence) thoroughly.
    - This will help understanding model & data skew/bias/anomalies, revealing problems in data labeling and cleaning/preprocessing.

Available External Material:

- Streamlining medical software development with CARE lifecycle and CARE agent: an AI-driven technology readiness level assessment tool

*Words marked with a star is defined in the Dictionary in the bottom of the document.

Prepare Technical Implementation

Up to 1 year

Primary Stakeholders:

- Data Engineer

Actions:

- Prepare technical implementation by creating coding language, involve stakeholders, and define end- and first users.
    - Examples of coding language could be: Python, Java Script, C++ etc.
- Initiate a dialogue with the Hospital's IT-Department to ensure that the model can be integrated in the already existing IT-infrastructure.
    - Ensure close collaboration to assess integration with existing systems.

Available External Material:

- Exploring the complex nature of implementation of Artificial intelligence in clinical practice

Refine Commercial Development Plan

Up to 6 months

Primary Stakeholders:

- Project Manager
- Company

Actions:

- At this point it is beneficial to revisit the project plan you made in the ""Idea"" phase to make an estimate of the potential market, number of potential users, feedback from potential users and more thorough analysis of the competitive landscape.
- Assess competition. Have other companies developed a similar solution? What does the customers and other value drivers* think?

Conduct Design Verification* of your Medical Device

Primary Stakeholders:

- Regulatory Expert
- Company

Actions:

- Perform studies and tests to confirm the device agrees with design requirements in General Safety and Performance Requirements (GSPRs)*.
- AI system software must meet requirements constituted by Chapter 2 of EU AI Act*.
- Develop labels and user instructions.

Meet the Identification & Information Requirements

3-6 months

Primary Stakeholders:

- Company

Secondary Stakeholders:

- Regulatory Expert

Actions:

- Start taking care of transparency and traceability of your device by complying requirements related with European database on Medical Devices (EUDAMED)*.
    - Develop labels and user instructions.

Provide Relevant Validation Documentation

Primary Stakeholders:

- Regulatory Expert
- Company

Actions:

- Demonstrate compliance with applicable GSPRs (General Safety and Performance Requirements)*, especially in term of analytical and clinical performance information

*Words marked with a star is defined in the Dictionary in the bottom of the document.

(as an analysis of performance evaluation/clinical evaluation) and stability studies (claimed shelf life*, in use stability and shipping stability studies).

Obtain Regulatory Approval

Primary Stakeholders:

- Company

Actions:

- Contact your Notified Body*.
- This has to be done before the validation test.
- Be aware of different scope of activity within notified bodies and its limited capacity. They can help with the regulatory elements going forward.

Available External Material:

- List of Notified Bodies (NANDO)

Prepare for Conformity Assessment*

Primary Stakeholders:

- Company

Secondary Stakeholders:

- Regulatory Expert

Actions:

- Complete and prepare your technical documentation for external audit* according to concrete conformity assessment* procedure.

*Words marked with a star is defined in the Dictionary in the bottom of the document.

5. LAUNCH - Product Launch & System Qualification

Introduction

While preparing your AI solution for market entry is crucial to plan how to launch your product. Key activities include completing the conformity assessment* and securing CE-marking*. You will also register the product in European database on Medical Devices (EUDAMED)* and, if exporting, apply for a Free Sales Certificate*.

A business plan will be developed to highlight the product's clinical benefits to end-users and key opinion leaders (KOL)*, alongside conducting a Health Technology Assessment (HTA)*. Finally, planning for implementation ensures that the end-users* are prepared, and potential challenges are addressed, paving the way for a successful launch.

Outcome

The outcome will be a fully certified AI solution ready for deployment, having completed CE-marking*, conformity assessment*, and regulatory registration. A clear business and implementation plan will support uptake, while a Health Technology Assessment (HTA)* results and promotional materials will help communicate value to users and decision-makers. The solution is now positioned for integration into clinical workflows and operational use.

Product Certification

Primary Stakeholders:

- Company

Actions:

- Conduct conformity assessment* procedure to certify your product.

*Words marked with a star is defined in the Dictionary in the bottom of the document.

Draw Up EU Declaration on Conformity

Up to 6 months

Primary Stakeholders:

- Company

Actions:

- EU declaration of conformity* states on reaching the compliance with regulatory requirements of the product.

CE-Marking

Up to 6 months

Primary Stakeholders:

- Company

Actions:

- Apply for CE-marking of the device.

Apply for Certificate of Free Sale

Up to 6 months

Primary Stakeholders:

- Company

Actions:

- In case of EU/European Economic Area (EEA)* export apply for a Certificate of Free Sale (CFS)*.

Register your Product in the European Database on Medical Devices (EUDAMED)

Up to 2 months

Primary Stakeholders:

- Company

Actions:

- Once you have ensured transparency and traceability of your AI solution in line with the requirements mentioned in the "Validate" phase, the AI solution needs to be registered in the European database on medical devices (EUDAMED)* to support regulatory transparency.

Create the Business Plan and Materials

Up to 2 months

Primary Stakeholders:

- Company

Actions:

- Pitch your AI solution's key advantages (e.g. clinical utility, novelty, cost, benefit) to end-users, buyers and key opinion leaders (KOLs)*.
- Build your marketing plan around your competitive advantage based on a SWOT analysis (Strengths, Weaknesses, Opportunities, and Threats)*.
- Find the right customers with the STP Model (Segmentation, Targeting and Positioning)*.
- Be visible at meetings and appropriate conferences.
- Set the marketing budget accordingly.
- Find and select distributors.

Perform the Health Technology Assessment (HTA)

1+ year

Primary Stakeholders:

- Company

Secondary Stakeholders:

- Clinician
- Project Manager

Actions:

- Consider contacting a Health Technology Assessment (HTA)* Agency for support.
- Examples of different Health Technology Assessment (HTA)* frameworks that has been developed in the different countries:
    - DigiHTA(Finland)
    - DIGA (Germany)

- MAS-AI (Denmark)
- Or others for your respective country.

Available External Material:

- To buy or not to buy—evaluating commercial AI solutions in radiology (the ECLAIR guidelines)
- Suitability of the Current Health Technology Assessment of Innovative Artificial Intelligence-based Medical Devices: Scoping Literature Review
- Artificial Intelligence and Health Technology Assessment: Anticipating a New Level of Complexity
- Health technology assessment framework for artificial intelligence-based technologies
- Dynamic HTA for digital health solutions: opportunities and challenges for patient-centered evaluation

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Plan and Implement

Primary Stakeholders:

- Clinician
- Company
- Project Manager

Actions:

- Identify the first users of the AI solution, define their implementation roles, and establish a plan for managing potential issues during launch.

    - For concrete steps, see: Guideline for Adoption and Implementation based on Change Management*.
- There should be explicit guidelines for user training and support, along with steps to assess interoperability with existing hospital systems including training programs for end-users. This would help ensure smooth adoption of the AI solution.

Available Internal Material:

- Initiation

6. DEPLOY

Introduction

During deployment, the priority is to seamlessly integrate your AI solution into the hospital's IT-infrastructure, ensuring compatibility with existing systems, technologies, and clinical equipment, while effectively managing operational challenges. Change management* is essential, requiring continuous evaluation and fostering user ownership to embed the solution into daily routines. Collecting user feedback will help improve product quality and maintain data traceability*. Post-implementation evaluations are crucial for ongoing enhancement, while post-market surveillance* ensures compliance with regulations and monitors product performance. Vigilance measures must also be in place to address safety concerns and uphold patient safety.

Outcome

The outcome will be the successful integration of the AI solution into clinical workflows, supported by continuous performance monitoring and user feedback. Real-world data will be collected to assess clinical effectiveness, usability, and safety. Post-market surveillance* and vigilance processes will ensure regulatory compliance and enable ongoing improvements, safeguarding patient outcomes and supporting long-term adoption. Post-market surveillance should be an ongoing process after the AI solution has been deployed as illustrated in The Iterative Process Model.

Support Integration of your Solution to the Hospital IT-Environment

1+ year

Primary Stakeholders:

- Company
- Data Engineer

Secondary Stakeholders:

- Project Manager

Actions:

- Integrating a technical solution into a hospital's IT-environment can be a real challenge. To address this, you have been working with IT-Departments and vendors since the ""Develop"" phase and have identified compliance requirements.
- Some laboratory instrument providers are more open for allowing access to their Application Programming Interface (API)* or even source code enabling seamless technical integration.
- Reach out to the Hospital's IT-Department to ensure a proper technical integration.

Assessment of Change Management in Hospitals

Primary Stakeholders:

- Clinician
- Company
- Project Manager

Actions:

- To accomplish this step, there should be both continuous evaluation during the implementation process and after each stage, and there should be a sense of ownership, and the new products should be used in daily routines. Therefore, it is necessary to:
  - Encourage a sense of ownership among staff can be achieved by involving them in the decision-making and planning processes
  - Integrate the new product into daily routines through adequate training and support can promote adoption and minimize resistance
  - Receive regular feedback from users should also be gathered to refine processes and enhance overall effectiveness
  - Reach out to the Hospital's IT-Department.

Available External Material:

- PROBAST+AI: an updated quality, risk of bias, and applicability assessment tool for prediction modelsusing regression or artificial intelligence methods

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*Words marked with a star is defined in the Dictionary in the bottom of the document.

Monitoring and Feedback

1+ year

Primary Stakeholders:

- Company
- Clinician

Actions:

- Create traceability and a data provenance chain*.
- **Note**: Since AI tools changes, it is important to have a process on how to monitor and collect feedback from the clinicians/end-users (e.g. on malfunction or usability problems) to make necessary optimizations to local environments (which might cause MDR reevaluation) and in the end improve the product quality.
- Contact Hospital's IT-Department.

Available External Material:

- Monitoring performance of clinical artificial intelligence in health care: a scoping review

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Clinical Evaluation

1+ year

Primary Stakeholders:

- Company
- Clinician

Actions:

- Post-implementation evaluation becomes a key part of the learning process when working with AI solutions and is important for ensuring that the AI solution is adapted and improved over time. Therefore, the evaluation plan that was created pre-implementation needs to be conducted.
  - Contact Hospital's IT-Department.
- Revisit the clinical evaluation plan in the "Develop" phase.

Available External Material:

- AI-induced Deskilling in Medicine: A Mixed-Method Review and Research Agenda for Healthcare and Beyond

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Post-market Surveillance* for Product Life-cycle Management

Up to 2 months

Primary Stakeholders:

- Company

Actions:

- Are there any potential new products arising based on the evaluation?

Post-market Surveillance* for Regulatory Purposes According to MDR/IVDR*

Up to 2 months

Primary Stakeholders:

- Company

Actions:

- Gather and analyze data on quality, performance and safety of the device to update on your product in a timely manner.
- Maintain your Quality Management Systems (QMS)*.

- Follow up on the regulatory landscape.

Vigilance

1+ year

Primary Stakeholders:

- Company

Actions:

- Take appropriate measures and submit timely incident reports, when necessary, to ensure patient safety.
- **Note**: You are always obligated to report any incident and should in this case know who to contact and report to.

Dictionary

Term	Description
AI Act	The EU AI Act is the first-ever comprehensive legal framework on AI worldwide. The aim of the rules is to foster trustworthy AI in Europe.
Algorithm development plan	Algorithm development is the process of exploring different approaches to solve problems by defining a computational process that satisfies system specifications.
Analytical performance	The ability of a device to correctly detect or measure a particular analyte.
Application Programming Interface (API)	API is a set of protocols and tools that allow different software applications to communicate and exchange data, features and functionality.
CE-marking	CE-marking is what manufacturers use to indicate that a product meets relevant EU legal conformity standards in terms of safety, health and environmental protection.
Certificate of Free Sale	A Certificate of Free Sale (CFS) is an official document that confirms that a medical device is legally marketed and freely sold
Change management	A structured process aligning technical integration with human factors to boost readiness, adapt workflows, and build trust for safe, effective AI adoption.
Clinical performance	Clinical performance in AI refers to how accurately, reliably, and safely an AI system supports clinical tasks, decisions, or outcomes in real-world settings.
Conformity assessment	Medical conformity assessment in AI is the process of verifying that an AI-based medical device meets regulatory, safety, and performance standards before market entry.
Cost-effectiveness Analysis	CEA measures how much benefit is gained per euro spent, using outcomes like life expectancy or emissions reduced. It compares interventions or implementation methods.
Data Act	The Data Act is a law designed to enhance EU's data economy by improving access to industrial data, ensuring fair use, and clarifying who can use what data and how.
Data anonymization	Data anonymization is the process of irreversibly altering data so individuals cannot be identified, directly or indirectly, even when combined with other information.
Data curation	A managed process where data is cleaned, documented, standardized, and linked across its lifecycle, including versioning, merging, and metadata annotation.
Data dictionary	A centralized repository defining data attributes, formats, and relationships of data elements in a database to ensure consistency and effective data management.

Data lakes	A repository storing structured and unstructured data at any scale, enabling analytics, real-time processing, and machine learning without prior data structuring.
Data provenance chain	Data provenance chain is the documented history of data, tracking its origin, transformations, and movements to ensure accuracy, trust, and accountability.
Data pseudonymization	Pseudonymization is processing personal data so it cannot be directly linked to an individual without additional information, which is stored separately and protected.
Data traceability	Data traceability tracks the full data lifecycle, ensuring transparency, reproducibility, and accountability by documenting data origin, changes, and impact.
Design verification	Design verification ensures a product's design meets requirements and functions as intended before implementation.
End-user	An end-user is the individual or group, such as healthcare professionals, researchers, or patients, who directly interacts with or benefits from the AI solution.
EU Declaration on conformity (DoC)	DoC is a mandatory document where manufacturers declare their products comply with EU laws and take full responsibility for compliance.
European database on Medical Devices (EUDAMED)	EUDAMED is a database offering an overview of medical devices in the EU by integrating systems to share info, boosting transparency and coordination among member states.
European Economic Area (EEA)	The EEA groups together the 27 EU Member States and 3 European Free Trade Association countries in a single market subject to the same rules.
External audit	An external audit refers to an independent review of an organization's financial statements and related operations to ensure accuracy and compliance with applicable laws and regulations.
Freedom To Operate (FTO)	FTO is a legal assessment that evaluates whether a product can be developed, manufactured, and sold without infringing on existing patents, trademarks, or other intellectual property rights.
GDPR	GDPR is an EU regulation strengthening and harmonising EU/EEA procedures concerning the collection, storage, processing, access, use, transfer and erasure of personal data.
General Safety and Performance Requirements (GSPRs)	GSPRs, in MDR and IVDR Annex I, set essential safety and performance standards for medical and diagnostic devices.
Gold-standard methods	Gold-standard methods are the most reliable and widely accepted procedures used to ensure accuracy and validate new approaches.
Governance Structure	A governance structure defines roles, policies, and processes to guide AI development and oversight, ensuring accountability, ethics, risk management, and compliance.

Health Technology Assessment (HTA)	HTA is a transparent process that helps decision-makers use evidence on technologies to link research with healthcare policy decisions.
In Vitro Diagnostics Regulation (IVDR)	The IVDR (EU 2017/746) regulates the safety and performance of in vitro diagnostic devices to improve patient safety and device reliability in the EU.
Intellectual Property Rights (IPR)	IPR are legal protections granted to creators and owners of intellectual property, enabling them to control, use, and benefit from their inventions, designs, or artistic works.
ISO standards	ISO standards are international guidelines ensuring quality, safety, efficiency, and interoperability across industries.
Key assay parameters	Key assay parameters in clinical validation—like sensitivity, specificity, and accuracy—that demonstrates how reliably a test detects or measures a clinical condition.
Key opinion leaders (KOLs)	KOLs are trusted experts in healthcare whose insights guide AI development, support validation, and influence clinical adoption in real-world settings.
Manufacturer's obligation	In accordance with MDR, manufacturers must ensure device safety, compliance, labeling, surveillance, documentation, and report safety issues.
Market position	Market position refers to how the consumers perceive a brand or product versus competitors, based on factors like quality, price, and benefits.
Market size analysis	Market size analysis is an analysis of the total number of potential clients or buyers in a particular market segment.
Medical Device Regulation (MDR)	The Medical Device Regulation (MDR) (EU) 2017/745 is a regulation by the European Union that governs the safety and performance of medical devices.
Minimum Viable Product (MVP)	MVP is a version of a product with just enough features to be usable by early customers who can then provide feedback for future product development.
Notified Body	A Notified Body is an EU-designated organization that assesses product conformity when third-party evaluation is required, ensuring compliance before market entry.
Open-source	Open-source refers to software or projects whose source code is freely available for anyone to view, use, modify, and distribute, typically under a permissive license.
Person Responsible for Regulatory Compliances (PPRC)	A PRRC ensures regulatory compliance in manufacturing and post-market activities. MDR requires manufacturers and representatives to appoint a qualified person for this role.
Post-market surveillance	Post-market surveillance monitors a medical device's safety and performance after release to ensure compliance and detect risks.

Product life-cycle management (PLM)	PLM manages a product's lifecycle from inception to disposal, integrating people, data, processes, and systems to support companies and partners.
Proof-of-principle	Proof-of-principle is a demonstration that a concept or technology is feasible and works as intended in a preliminary or experimental setting.
Public-Private-Innovation collaboration contract (PPI contract)	A PPI contract is an agreement between public sector and private companies to jointly develop and implement innovative solutions in public services.
PubMed	PubMed is a free database with 38M+ biomedical citations and abstracts, aiding health research. It links to full texts when available from other sources.
Quality Management System (QMS)	QMS is a set of tailored processes and policies that standardize and improve quality to boost customer satisfaction across business operations.
Quality model	Quality models provides a framework to set data quality requirements, define measures, and guide evaluations, emphasizing ongoing management beyond development.
Research & Development (R&D)	R&D is the process of exploring new knowledge and creating innovative products, services, or technologies through systematic investigation and experimentation.
Retrospective validation	Retrospective validation tests an AI solution's performance on historical data to verify accuracy and reliability before real-world deployment.
GDPR Risk assessment	GDPR risk assessment identifies and evaluates risks to personal data, ensuring compliance and applying measures to protect data privacy and security.
Scientific validity	Scientific validity under MDR means a device accurately performs its intended function, supported by reliable scientific evidence, ensuring safety and compliance.
Segmentation, Targeting and Positioning (STP)	STP is a marketing process that divides a market into segments, selects key segments to focus on, and positions products to appeal to those segments.
Shelf life	Shelf life of an AI solution is the time it remains safe, effective, and compliant, including physical durability and model accuracy.
Standard Operating Procedures (SOP)	SOPs are detailed, written guidelines that outline consistent, standardized processes for performing tasks in an organization.
SWOT-analysis	SWOT analysis evaluates Strengths, Weaknesses, Opportunities, and Threats by assessing internal and external factors to maximize positives and minimize negatives.
Tech Transfer Office (TTO)	A TTO facilitates commercialization of research through licensing, patents, partnerships, and spin-offs to maximize intellectual property use.

Testing chain	A testing chain is the sequence of steps used to evaluate a product or system, ensuring it meets standards and functions correctly from initial tests to final validation.
TRL	Technology Readiness Levels are a measurement system used to measure tech maturity on a scale from 1 (concept) to 9 (fully deployed).
UX designer	A UX designer enhances user satisfaction by researching, prototyping, and testing to create intuitive, user-centered digital experience.
Value drivers	Value drivers are key factors that impact an AI solution's success, like cost-effectiveness, outcomes, efficiency, innovation, compliance, and user adoption.
Verification plan	A verification plan outlines the required level of accuracy and the process to ensure the algorithm meets specified performance standards.

CAIDX

– CLINICAL AI-BASED DIAGNOSTICS

About the project

The project CAIDX establishes cooperation between artificial intelligence (AI) providers and healthcare institutions to help healthcare professionals integrate AI, and thus improve diagnostics and treatment.

Implementation: January 2023 - December 2025

Project partners

- Innovationsklinikken (Aalborg Universitetshospital) (Lead partner)
- Wroclaw Technology Park
- BioCon Valley
- Tartu Biotechnology Park
- Lower Silesian Centre of Oncology, Pulmonology and Hematology
- Region Skåne
- Innovation Skåne
- Rostock University Medical Centre
- AUH Innovation, Aarhus Universitetshospital
- Danish Life Science Cluster
- The wellbeing services county of Southwest Finland
- Business Turku

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