Interreg Baltic Sea Region

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RESILIENT ECONOMIES AND COMMUNITIES

CAIDX

CAIDX TOOL #4

GAME PLAN

For implementation managers responsible for integrating AI solutions in clinical settings.

Background

The Game Plan can be used when public healthcare has identified a need, problem or a challenge that requires a solution. The Game Plan is supposed to be a tool that supports clinicians/researchers in planning and structuring an AI innovation project. It is supposed to be used at an early stage, to highlight the factors that will decide the most suitable path for a development project.

This document includes explanations and instructions on how to use the Game Plan. The Game Plan is mainly intended for clinicians/researchers who have already identified a clinical need to guide them to the most suitable form of innovation project. It can also be used as a guide for companies and AI developers to better understand how to run innovation projects with a public hospital.

Choice of path

There are four different paths that innovation projects can take: Research collaboration; In-house research and development; Co-development; or Purchase. Which path to take depends on certain background factors (see “Preparations before choosing a path” and “Check list” in the Game Plan.

The specific goal with the Game Plan is to support clinicians/researchers in making the right decision on which path to take, based on these background factors. The ultimate goal of the Game Plan is to secure that a solution to the identified clinical need can be implemented within the clinical routine setting as early as possible.

Before using the Game Plan, the clinicians/researchers should have identified a clinical need. The CAIDX tool ‘Need Identification’ can support with identifying and specifying the need.

Research collaboration

This refers to a research collaboration between public healthcare and the industry, with the **goal of generating new knowledge, insights and testing ideas** rather than developing a final solution which can be implemented.

This path should be chosen when there are no existing solutions on the market or even close to the market. Research collaborations are exempt from procurement legislation. However, it can still be advisable to carry out a procurement to select and secure the most competent partner, and to ensure an open and transparent process. It is then a “Pre-commercial Procurement” (PCP).

Note that there is no arrow from path A (Research collaboration) to Implementation in the Game Plan, since proof of concept is the final goal of a research collaboration. Another path should be chosen to go from proof of concept to a final solution that can be implemented.

In-house research and development

This refers to research and/or development of a potential innovation within one’s own organization. This path should be considered **if there are no available solutions on the market** for the specific need, and the market does not show interest in developing a solution for the need.

This path could be chosen very early on in the development within a new area to create knowledge within the organization. Such a process could continue with full development of a product in-house or transform into Research collaboration (path A) or Co-development (path C) project, depending on TRL-levels and the interest on the market. Path B (In-house research and development) is only possible if the requirements in MDR article 5(5) are met.

Note the arrow pointing to the left from path B in the Game Plan, indicating that depending on how the project evolves (e.g., a solution on the market is identified), there might be reasons to go back and choose a new path.

Co-development

This refers to the collaboration between public healthcare and the industry regarding **the development and implementation of products and services following a public procurement**, also referred to as "Public Procurement of Innovation" (PPI).

Co-development includes joint activities for development and implementation of solutions not readily available on the market, but not too far from the market. The actors involved contribute with necessary unique skills and roles, and their responsibilities are clearly defined.

To ensure that this is the right path or strategy to choose, a thorough analysis of the wider context, i.e., business intelligence and market analysis is required, and a broad market dialogue is recommended. This path is appropriate when there are suitable solutions under development that are sufficiently mature to enable development of a final solution that can be implemented.

Purchase

This refers to a straight forward **purchase of a solution that is readily available on the market**. Choose this path when there is at least one identified solution on the market that fits with the clinical need. Start this process with an early market dialogue, for example through meetings and external referral, to ensure that the available solutions in fact match your need.

THE GAME PLAN

For publicly initiated development and dissemination of ideas and solutions within AI in public healthcare

Identified NEED!
(see specific CAIDX tool)

Preparations before choosing a path

1. Expected benefit/value

- ❑ Better clinical outcomes?
- ❑ Better utilisation of resources?
- ❑ Better patient experience?

2. Wider context

- ❑ What is already on the market?
- ❑ Is there scientific evidence?
- ❑ Is data available?
- ❑ What are other regions/ countries doing?
- ❑ Is there anything similar within other sectors?

3. Stakeholders

- ❑ Who owns the need?
- ❑ Who is the end user/s?
- ❑ Who will administrate the solution?
- ❑ Is there a national interest?

Planning and choice of path

Use the checklists on the next page!

Choose a path!

A → Optional: competitive tendering → **RESEARCH COLLABORATION** Proof of Concept/knowledge/insight

Analyse outcome of R&D. Go back to planning and choice of path.

B → **IN-HOUSE RESEARCH & DEVELOPMENT**

If the circumstances have changed, go back to planning and choice of path.

C → Competitive tendering → **CO-DEVELOPMENT**

D → Competitive tendering → **PURCHASE**

Project realisation

Implement

After choosing a path, go to Clinical AI Pathway for more information on how to continue
(see specific CAIDX tool)

Checklist

A RESEARCH COLLABORATION

Select A if:

- ❑ **There is no solution on the market**
- ❑ **The main aim is to generate knowledge, insights and/or PoC (Proof-of-Concept)**
- ❑ **TRL* 1-4**

Also take account of:

- ❑ Identify potential companies for your research collaboration project.
- ❑ There should be an interest in the organisation to explore a new, untested area.
- ❑ Plan how results should be managed and communicated to avoid conflict of interest in a potential future procurement process.
- ❑ Make sure to comply with the rules concerning government subsidy.
- ❑ Consider whether you should choose research partners through competitive tender.

B IN-HOUSE RESEARCH & DEVELOPMENT

Select B if:

- ❑ **There is no solution on the market**
- ❑ **The main aim is to generate knowledge (i.e. research) and/or to develop and implement a new solution in the organisation**
- ❑ **TRL* 1-9**

Also take account of:

- ❑ In order to choose Path B, there should not be any available products on the market that address your need.
- ❑ Clarify future ownership and administration including potential CE certification.
- ❑ An in-house developed product must not distort or block competition on the market (Treaty on the Functioning of the European Union (TFEU), specifically articles 101-109).
- ❑ Make sure to comply with MDR article 5(5) regarding in-house developed products.

C CO-DEVELOPMENT

Select C if:

- ❑ **There is no CE-marked solution on the market, but private companies have solutions under development**
- ❑ **The main aim is to implement a new solution in the organisation**
- ❑ **TRL* 4–7 (9)**

Also take account of:

- ❑ Identify potential companies for your co-development project.
- ❑ Clarify future ownership and administration including potential CE certification.
- ❑ Make sure there is financing for development and potential purchase.
- ❑ Consider whether a business model needs to be developed.
- ❑ Make sure there is resources and expertise for procurement, including procurement of innovation.
- ❑ (TRL 9: Path C could be chosen when there is interest in co-developing services/ processes around an existing product.)

D PURCHASE

Select D if:

- ❑ **There is a solution on the market**
- ❑ **The main aim is to implement a new solution in the organisation**
- ❑ **TRL*9**

Also take account of:

- ❑ Identify potential products on the market that suits your need.
- ❑ Start a dialogue with potential suppliers.
- ❑ Secure resources and expertise for procurement.

About the Game Plan

Purpose: The Game Plan can be used when public healthcare has identified a need, problem or a challenge that requires a solution. The Game Plan is supposed to be a tool that supports clinicians in planning and structuring an AI innovation project. It is supposed to be used at an early stage, to highlight the factors that will decide the most suitable path for a development project.

For whom: This document is mainly intended for clinicians who have already identified a clinical need to guide them to the most suitable form of innovation project. The Game Plan can also be used as a guide for companies and AI developers to better understand how to run innovation projects with a public hospital.

Instructions: Please read the "Introduction to the Game Plan" for instructions on how to use the Game Plan and for more thorough descriptions of the various paths.

Credit: The Game Plan was originally developed by Swelife for all types of projects within healthcare. It has been refined within the CAIDX project to specifically address the development of AI solutions.

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TRL, Technology Readiness Level

TRL describes the degree of maturity of a technology.

TRL 0 First principles: A stage for greenfield research.
TRL 1 Goal-oriented Research: Moving from basic principles to practical use.
TRL 2 Proof of Principle (PoP) Development: Active research and development (R&D) is initiated.
TRL 3 Systems Development: Sound software engineering.
TRL 4 Proof of Concept (PoC) Development: Demonstration in a real scenario.
TRL 5 Machine Learning "Capability": The R&D to product transition.
TRL 6 Application Development: Robustification of machine learning (ML) modules, specifically towards one or more use-cases.
TRL 7 Integrations: ML infrastructure, product platform, data pipelines, security protocols.
TRL 8 Mission-ready: The end of system development. CE certification is completed.
TRL 9 Deployment: Monitoring the current version, improving the next.

TRL description from: Lavin, A., Gilligan-Lee, C.M., Visnjic, A. et al. Technology readiness levels for machine learning systems. Nature Communications 13, 6039 (2022). https://doi.org/10.1038/s41467-022-33128-9.

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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