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?

Use the checklists on the next page!

Choose a path!

Planning and choice of 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.

Interreg Baltic Sea Region — Co-funded by the European Union

RESILIENT ECONOMIES AND COMMUNITIES
CAIDX

interreg-baltic.eu/project/caidx/

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.