# Guidelines for testing in clinical environments

Who are these guidelines for?

These guidelines are for testbed staff within the Nordic testbeds, within NoTeB, and for the companies contacting any of the testbeds.

The guidelines have been developed in collaboration with the testbeds in NoTeB, during a project funded by Nordic Innovation. The guidelines are a combination of verified local best practices, adapted to the surrounding eco-systems, and the practical pan-Nordic experience, generated from performing clinical tests, in real cases, submitted by companies.

What is testing in a clinical testbed context?

Testbeds comes in many shapes and forms and there is not one answer to what testing is, in the clinical testbed context. In NoTeB, we have investigated the services provided by the testbeds, at the university hospitals, and we choose to answer this by exemplifying testing, with the following tests: Idea Validation Workshop, Product Requirement Review Meeting, Usability Test, Clinical Trial, Pilots and Healthcare Economics Analysis. These guidelines will provide guidance on how these tests are conducted in the clinical testbeds, within NoTeB.
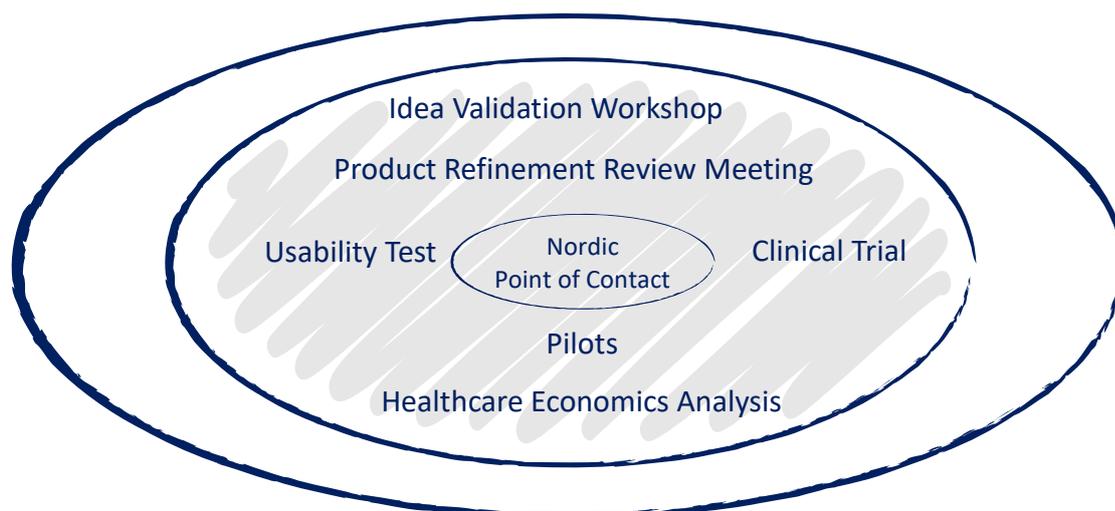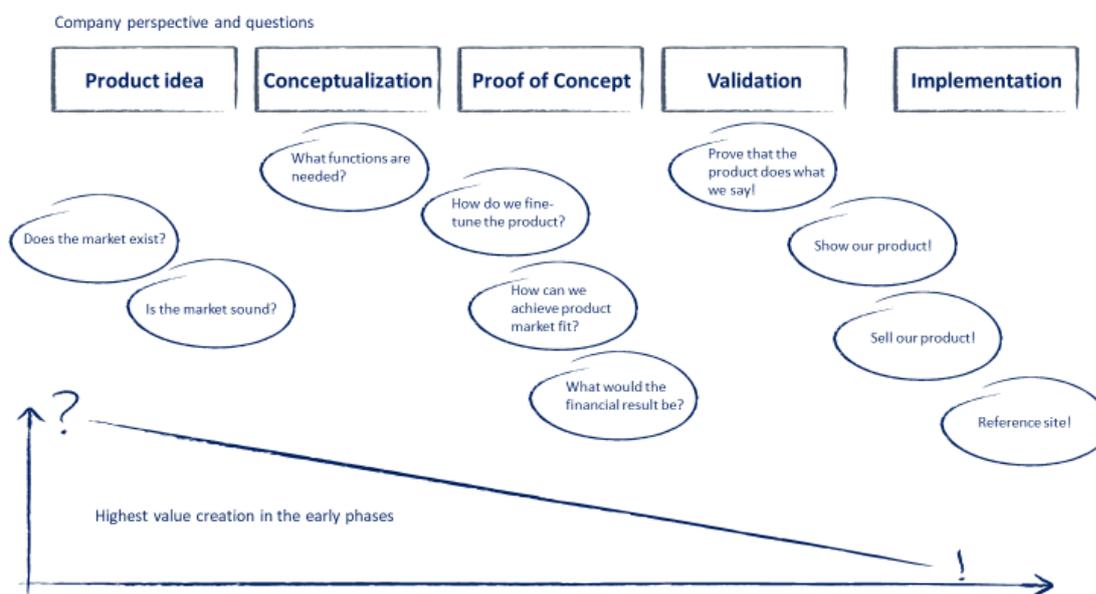

The testbeds offer opportunities for collaboration and co development through test. A test is however, not a seal of quality, and the purpose of a test should not primarily be for the purpose of selling the product. The clinical testbed services may be delivered by the testbed or through a partnership with

another organisation. Through the joint work in the NoTeB project, we know that the testbeds do provide more services than the examples given above. The services in focus for these guidelines are available from most of the Nordic testbeds, and their networks. In addition to the most common Nordic testbed services, we also discovered a need for a new function, which is the opportunity to have access to Nordic healthcare perspectives, in a convenient format. The new function Nordic Point of Contact addressing this need, has therefore been added as an additional perspective, in the service descriptions, for the clinical test services, within the guidelines.

The test services follow the companies through product development

The testbeds support the companies on their product development journey and have developed their clinical test services, to address these questions, throughout the test journey. When the product development journey is done properly: the right product is developed for the right need, at the right price, using the right business and payment model. The journey should also deliver the right clinical benefits, in terms of both patient and financial outcomes. The testbeds support the journey from product idea through conceptualisation, proof of concept and validation, to implementation. However, the total amount of testbed engagement varies and is highest in the early stages of the development processes. The illustration below describes the questions and the interaction with the testbed from a company perspective.

Company perspective and questions

| Product idea | Conceptualization | Proof of Concept | Validation | Implementation |

What functions are needed?

Prove that the product does what we say!

How do we fine-tune the product?

Does the market exist?

Show our product!

Is the market sound?

How can we achieve product market fit?

Sell our product!

What would the financial result be?

Reference site!

Highest value creation in the early phases

Guidelines for testing – five steps!

Testbed services delivered by the individual Nordic testbeds have been reviewed, and the outcome shows that all services are based on a five-step process: Type of test, Participants, Ethical considerations, Procurement checks and Test set-up.

| Type of test | → | Participants | → | Ethical considerations | → | Procurment checks | → | Test set-up |

These guidelines provide a checklist for each individual step, on a Nordic test level, and highlight the considerations and areas where local rules and regulations needs to be considered.

1. Type of test:

- ☐ Questionnaires
- ☐ Interviews
- ☐ Meetings
- ☐ Workshops
- ☐ Immersions
- ☐ Technical tests
- ☐ Clinical trials
- ☐ Pilots

Multiple tests may be required and the type of test, is defined in dialog with the company. The types of tests are mentioned in order following typical product development maturity, where questionnaires and interviews are more commonly used in the early development stages, such as product idea.

2. Participants

- ☐ Clinical staff - nurses, doctors, physiotherapists etc.
- ☐ Support staff - IT, economy, cleaning, procurement etc.
- ☐ Testbed staff or other participants from Nordic countries
- ☐ Facilities, meeting rooms and technology
- ☐ Transport and accessibility

Plan and focus on multidisciplinary teams, when identifying the participants, since this is shown to increase value for both participants in/and for the testing company. Make use of different perspectives and organisational belonging when putting together the multidisciplinary test teams to capture upstream and/or downstream effects of the product. This approach will more likely lead to a faster development of the final product, that fits better into he overall healthcare scenario where it is to be used.

3. Ethical considerations

- ☐ Avoid involving patients, until necessary
- ☐ Circumvent bias
- ☐ Be updated and compliant to ethical rules and regulations

It is important to encompass the attitudes and feelings of patients and individuals in order to create a product that will be properly used. However, a company that is developing a product needs to think through both when to involve patients, and how. A common mistake is where the patient thinks there will be a solution our on the market shortly when in fact it will take several years. Follow ethical rules and regulations and involve supporting staff when possible. Bias is always difficult to avoid, but if the company is aware of the possibility it is easier to handle.

4. Procurement checks

☐ Plan for possible future procurements – avoid procurement risks
☐ Evaluate the test project from the perspectives of: transparency, equal treatment, non-discrimination, proportionality

It is important to handle procurement risks in order to avoid future problems related to unfair competitive advantages. If the company is aiming to sell their product to the public entity where the test is to be done, this is especially important. Risk reducing measures can be to publish test outcomes, limit tests to another entity or unit, etc. If questions remain, discuss potential issues with supporting procurement unit.

5. Test set-up:

☐ Perform risk analysis to identify relevant test cases
☐ Use pre-defined test protocols
☐ Communicate plans and conditions to participants and company

In the test set-up and design of the test protocol, it is very important to understand what the objectives are. It is worthwhile to spend some time going through the plan and thinking through possible outcomes, before starting the test. I.e. develop pre-defined test protocols before starting. Use experience from the Nordic testbeds and look for similarities and differences to tests on other markets and businesses. Focus on identifying strengths and weaknesses of the products, from a healthcare perspective. Make sure the product maturity is correctly assessed and never exaggerate its maturity.

The test journey steps

The definition of a successful test journey is when there has been a transfer of knowledge and experience. The outcome of a test may be unwanted or unexpected, but if knowledge and experience has been transferred and can be used in further development, it should be considered a success. The test journey is divided into the following four steps: Dialog, Contract, Test planning & testing and Report.

Dialogue → Contract → Test planning & testing → Report

The requirements for each of the steps, are described below.

1. Dialogue – Point of contact

   ☐ Establish common understanding of the product
   ☐ Define the stage of maturity of the product
   ☐ Discuss how to test with support from previous cases and neighbouring markets
   ☐ Agree on what and how to provide feedback, based on the maturity of the product and purpose of test
   ☐ Identify needs from a Nordic healthcare perspective

2. Contract

   ☐ Should contain non-disclosure conditions
   ☐ Should address IP-rights
   ☐ Should address remuneration

3. Test planning and testing

   ☐ Establish project plan including risk analysis etc.
   ☐ Establish appropriate test protocols
   ☐ Follow test protocols

4. Test Report

   ☐ Compile test results in agreed report format

Throughout the journey, it is important to focus on identifying and handling needs, and any information that may guide the companies and/or healthcare, to a faster and more successful implementation. The journey of testing is also about building experience and trust, through the collaboration.

Test service description

Selecting which test services to use, is established in dialogue between the testbed and the company. Three main test services and a supporting function has been identified to be available, fully or in part, from the Nordic testbeds, within NoTeB.

The three test services are:

- Idea and Product review
- Usability
- Clinical test

supported by the Point of Contact function.

The content and output from the test service follows the maturity of the product. The focus will change with the product development process, described with examples, below.
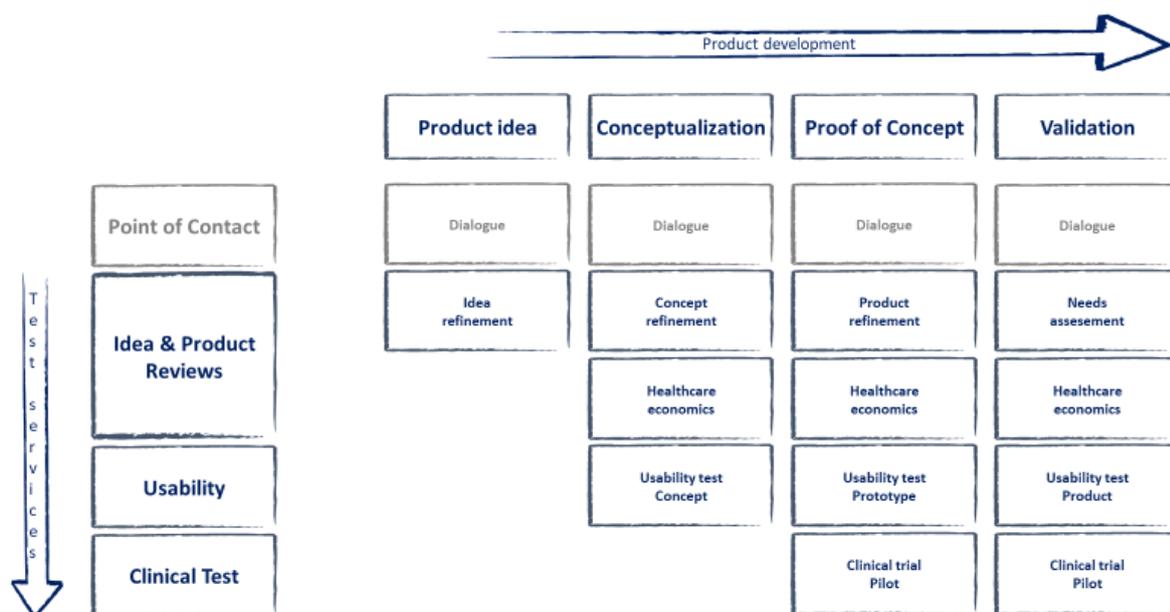
- The Point of Contact function is always based on dialogue, around receiving a question, reviewing the need for test, and giving advice on the appropriate next steps.
- Idea and product reviews are completed in order to assess the needs and refine the solution that matches, by identifying strengths and weaknesses. The reviews should be designed to cover clinical needs as well as organisational and financial aspects.
- Usability test are done to guide product development (formative) or to show that product requirements are fulfilled (summative).
- Clinical tests include clinical trials and pilots, which may include the generation of patient data. These tests may be done, in part, in the testbed and in part, by organisations, in the ecosystems surrounding the university hospital testbeds.

The function and services are described from four perspectives: Company questions, Service description, Roles and competences in testbed and Objective.

Function description: Point of Contact

Point of Contact

1. Company questions

    ☐ What testbed services are available

- ☐ Investigate current clinical and administrative processes
- ☐ What are the product requirements?
- ☐ Is there a Nordic healthcare perspective

2. Description

- ☐ Receive questions
- ☐ Review questions in a multidisciplinary context
- ☐ Advise company on next step. Advise is given based on available information and should not require start of investigation or test.

3. Roles and competences in testbed

- ☐ Be accessible and open to questions
- ☐ Have deep knowledge about clinical process, as well as the surrounding eco-system
- ☐ Skilled in testbed services and product development for clinical environments
- ☐ Use of questions and contacts to continuously improve processes

4. Objective

- ☐ Communicate services with local healthcare, Nordic healthcare, and connected testbeds, to drive growth and healthcare improvements

Service description: Idea and product review

Idea & Product Reviews

1. Company questions

   - ☐ Identify and verify product requirements
   - ☐ Verify ideas, concepts and products in development
   - ☐ Access previously identified problems and/or solutions within the clinical environment
   - ☐ Access data from clinical and/or administrative processes

2. Service description

   - ☐ Refinement of idea, concept or product through multidisciplinary review
   - ☐ Needs assessment report through multidiscipline review and research
   - ☐ Healthcare economics analysis on historical data
   - ☐ Healthcare economics analysis on generated data

3. Role and competence in testbed

   - ☐ Capability to organize, participate and document multidisciplinary review that delivers value to the company and the participants
   - ☐ Collect and compile information prior to review, through dialog
   - ☐ Match participants with company questions and development phase
   - ☐ Follow process for ethical questions, procurement checks and risk analysis
   - ☐ Follow test-set up process for review and/or healthcare economics analysis
   - ☐ Document and report outcome of review according to predefined format

4. Objective

   - ☐ Provide knowledge for development and validation, on how well a solution addresses identified needs, and the expected effect on productivity and costs, on healthcare
   - ☐ Horizon scanning, influence design of solutions and identify needs for change within the healthcare organization

Service description: Usability

Usability

1. Company questions

   - ☐ Request insights on usability during development
   - ☐ Verify that the design fulfils requirements on usability

2. Service description

   - ☐ Plan, test and report tests of usability in clinically relevant environments
   - ☐ Formative test of usability with a report describing the outcomes, based on qualitative data. Usability test can be based on interviews, recording of comments, photos and videos, and may include suggestions for improvements and changes.
   - ☐ Summative test of usability with a report describing the outcomes, based on quantitative data and outcomes, compared to set goals. Examples of data from summative tests are: measured time to learn, number of successful uses, number of questions raised during the test etc.

3. Role and competence in testbed

   - ☐ Capability to plan, test and report usability tests that can be used in product development and/or to show compliance with regulatory requirements
   - ☐ Identify and recruit participants for test
   - ☐ Identify clinically relevant test environments
   - ☐ Follow process for ethical considerations, procurement checks and risk analysis
   - ☐ Follow test-set up procedure for formative and summative tests
   - ☐ Document and report outcome of review, according to predefined format

4. Objective

   - ☐ Improve and validate usability of solutions intended for use in healthcare

Service description: Clinical Test

Clinical test

1. Company questions

   - ☐ Start a clinical trial
   - ☐ Access patient data or samples
   - ☐ Access data for a clinical evaluation

2. Service description

   - ☐ Provide contacts to eco-system and networks
   - ☐ Advice on general requirements for clinical test
   - ☐ Provide test alternatives without need for patient or patient data

3. Role and competence in testbed

   - ☐ Keep updated with networks for clinical trials and studies in quality registers
   - ☐ Keep updated with requirements in regulatory and ethical regulations and clinical trials
   - ☐ Identify and communicate test alternatives (that do not require patient involvement) without need for patient involvement

4. Objective

   - ☐ Accelerate development and introduction of safe and effective solutions in healthcare

The role of the Nordic testbed

The main purpose for all Nordic testbeds is to facilitate growth and improvements in healthcare, in parallel. Guidelines for testing in clinical environments describes the roles and test services by the Nordic testbeds, independent of the country of origin of the business idea, or the need it is matched to.

With these guidelines and the identified common test services, the individual testbeds, at the five university hospitals in NoTeB, are connected and function as one Nordic testbed.