Welcome to Nordic Proof Webinar & Matchmaking Event

June 2nd 2021

NordicProof

Nordic Innovation

Before we start

To run the webinar in the best possible way, please;

1. Unmute and turn off you camara
2. If you have questions, please use the chat functionality
3. Please register your full name in Zoom

NordicProof

Agenda

12:00 pm	Welcome and short intro to Nordic Proof and the program *Siri Stabel Olsen, Coordinator Nordic Proof*
12:10 pm	Navigating the regulations for e-Health companies. *Kami Faust, Regulatory Advisor at Norway Health Tech*
12:25 pm	Clinical Evaluation for Software as a medical device *Claudia Dannehl, Medical Device Manager at Link*
12:45 pm	An e-Health companies' journey from concept to submission *Anders Aune, CEO at Picterus*
1:00 pm	Closing of webinar. One2One meetings in separate online meeting rooms
3:00 pm	End program

NordicProof

Nordic Proof

Consortium of premium test facilites in the Nordics

NORDIC MEDTEST
For safer IT in Health Care

Danderyds Sjukhus
I TRYGGA, SÄKRA HÄNDER

Oslo University Hospital
Intervention Centre

HUS

SUNNAAS SYKEHUS

OULU HEALTH LABS

REGION H
Vihtek
Videncenter for velfærdsteknologi

Norwegian Smart Care LAB

Operated by

Norway Health Tech

Funded by

Nordic Innovation

Bent-Håkon Lauritzen
Coordinator Nordic Proof
bhl@norwayhealthtech.com

Experience/background

- Project leader Nordic Public Procurement of Innovation (PCP and PPI) and several procurement projects in Norway
- Business coach startup companies and project leader lean launchpad program
- Project leader innovation projects with Municipal sector and hospitals in Norway
- Lecturing at University of Southeast Norway
- Development of business parks and incubators
- Industry development projects for Norwegian Ministry of Foreign Affairs in the Balkan region
- Previous owner and CEO of Norwegians largest bookstore chain

Siri Stabel Olsen
Coordinator Nordic Proof
sso@norwayhealthtech.com

Experience/background

- 10+ years experience from industrial R&D chemistry
- 15+ years in commercial and leadership roles in the diagnostic- and medical device industry
- International experience - EU, China, USA
- B2B business development
- CEO for Skannex AS for 7+ years. A medical device company developing and supplying SW/HW products for point of care diagnostics
- Master of Science in Polymer Chemistry
- Master of Managment in leadership and strategy

Mission

Our network offers easy access to the most renowned health institutions and testing hubs within healthcare in the Nordics.

Professional expertise provides predictability and solid services based on real customer needs.

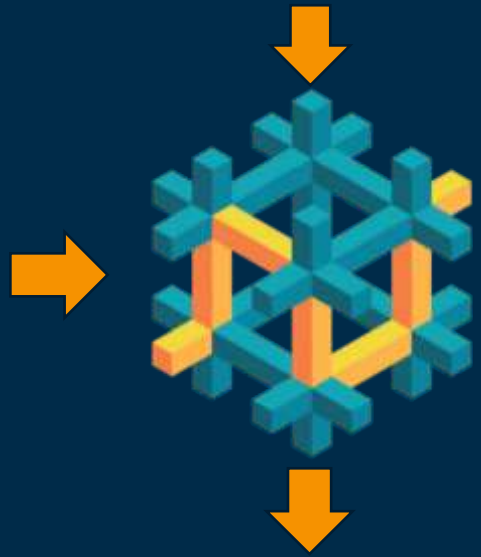
NordicProof

Nordic Innovation

Main objective

Requests from companies

Strategic areas and need driven innovation for Health Institutions



Effective and better healthcare services

New products and services that are targeted to the market

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Why is the Nordics a superior test arena?

Top three core qualities survey results[1)]

1. The Nordic region provides equitable healthcare to all
2. The Nordic healthcare system is characterized by high quality and knowledge
3. Nordic countries are early adopters of new treatments and technology

One door in

27 million people

Learn market needs and healthcare systems for future market entry!

1) Report:Strongholds and Qualities of the Nordic Health Tech Ecosystem, Menon Economics, 2018, © Nordic Innovation

What we offer to the health industry

- One point of contact to a network of world class health institutions in the Nordics.
- Efficient, transparent and on time services.
- Tested with Nordic quality and expertise from idea to finished product.

Nordic Proof – a way the get to know the Nordic market and their needs

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Services throughout your development cycle

Post-market studies

- Post market studies

Product requirement & User need

Access to experts. Can include one or several of below topics:

- Critical unmet need
- Clinical strategy
- Adoption hurdles
- Technical requirement
- Intended use
- Competitive landscape

Cost benefit analysis

Access to experts. Can include one or several of below topics

- Willingness and ability to pay for product
- Current clinical practice process mapping
- Reimbursement strategy & assistance in design of clinical program to support reimbursement goals
- Hypotheses of value based outcome with input from key opinion leaders

Development & Design Review

- Design Reviews supported by Key Opinion Leaders & Clinicians
- Evaluate early prototypes
- Determine if user needs are fulfilled

Product Verification & User need Validation

- Ensure the HW/SW design execute on the design concept
- Clinical evaluation of prototypes
- Clinical trial
- Confirm intended medical benefit
- Functional test
- Integration test
- System Level testing
- IT security testing
- Risk analysis
- Demonstrate value based outcome

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Fixed price workshop package

Content and process:

- Order the service package through our website
- Nordic Proof coordinator check availability of experts (2-3 experts per workshop) with relevant Nordic Proof partner(s).
- Nordic Proof coordinator create semi-structured interview guide with input from company.
- Selected Nordic Proof partner(s) recruit relevant experts.
- 1/2 day workshop conducted with company and recruited experts at partner(s) test facility.
- Nordic Proof partner(s) write report with findings and recommendations.

Price:
€3000 for one workshop including the development of interview guide
€2000 per additional workshop

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Case – Independence Gear

- Started out testing with innovation department at Sunnaas Hospital in their home market
- Scaled user test to VihTek in Copenhagen and Danderyd in Stockholm
- Launching first product to market
- Now starting to develop product number two together with users at Sunnaas hospital

“Without access to real life testing facilities at the Nordic Proof partners, we would not have products in the market, says Carl Christian Sole Semb in the Norwegian med-tech company Independence Gear”

Case – Rabmed – conducting a market study

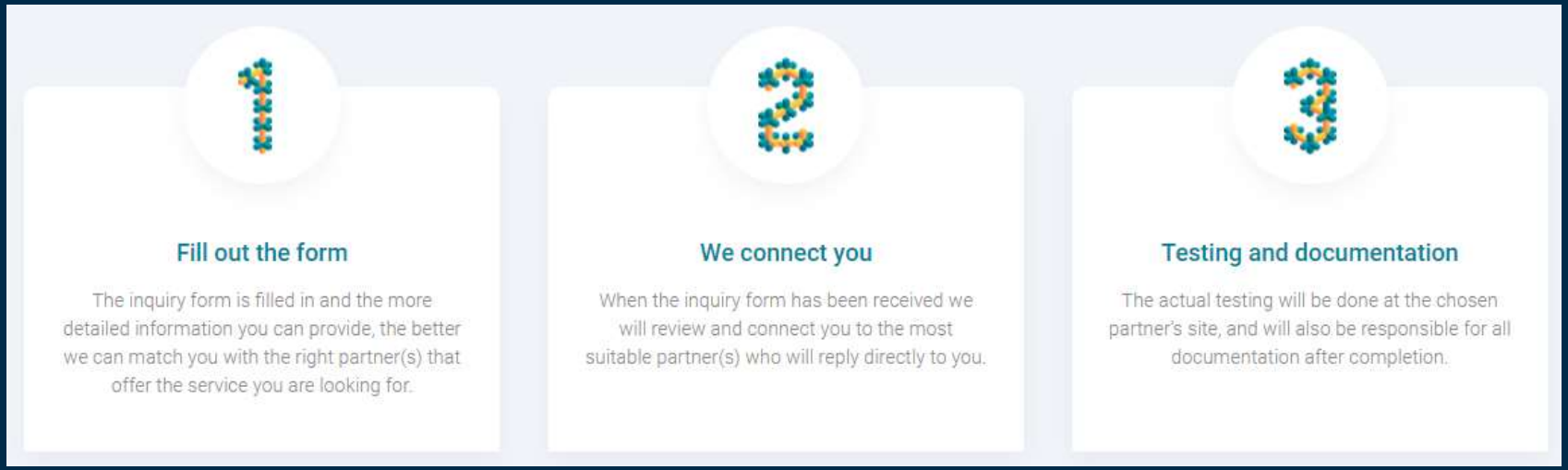
- Early phase prototype of needle-free connector for glass ampoules
- Designed an interview guide together with Nordic Proof
- Conducting one day on-site interview with health professionals
  - Helsinki
  - Stockholm
  - Oslo
- Each test facility wrote a sum up report from the interview
- The company got important feedback for their further development process and market strategy

“We came in selling the product as if we were doing a sales pitch. We soon realized that the meetings were most valuable to us if we sat back and allowed them to be brutally honest - almost prompting their most critical feedback”

Marius Andresen, serial entrepreneur

AmpuSeal

The process for Nordic Proof inquiries



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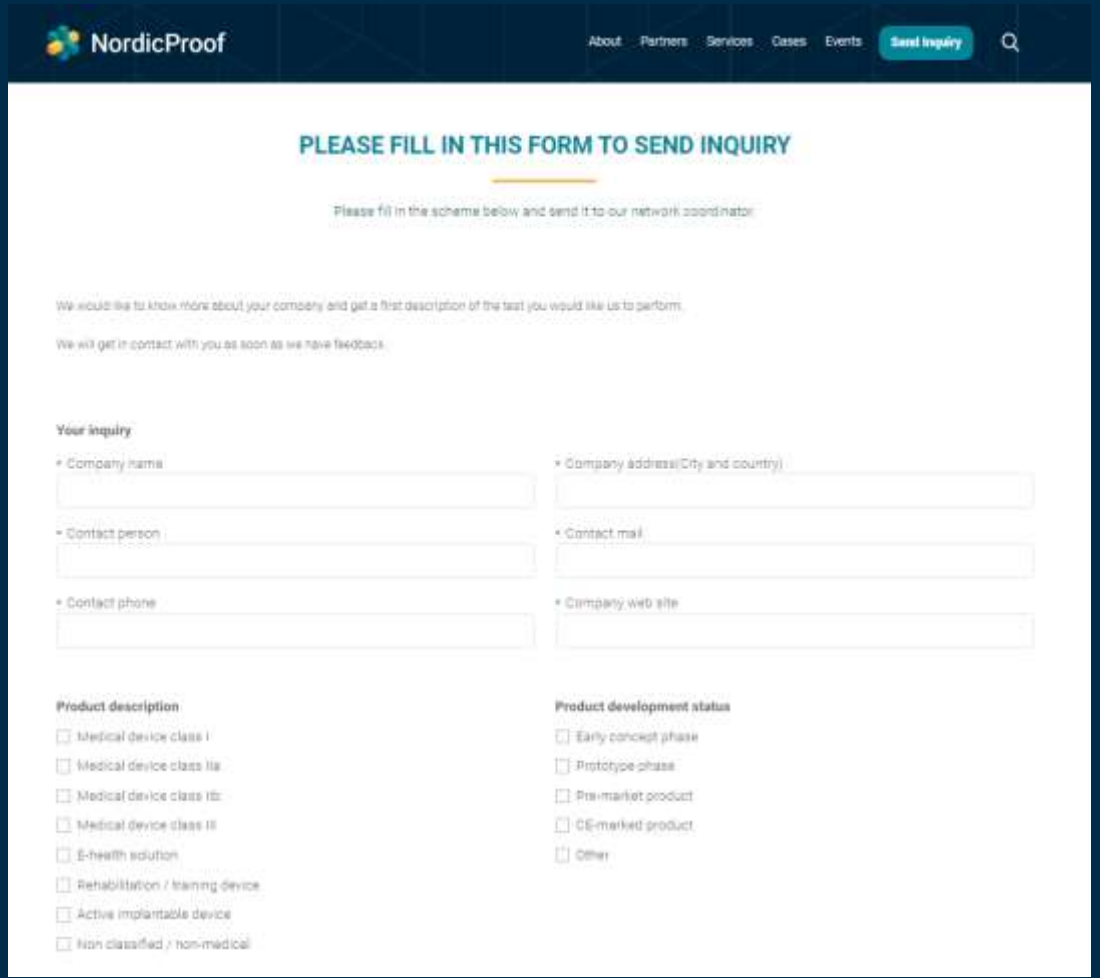

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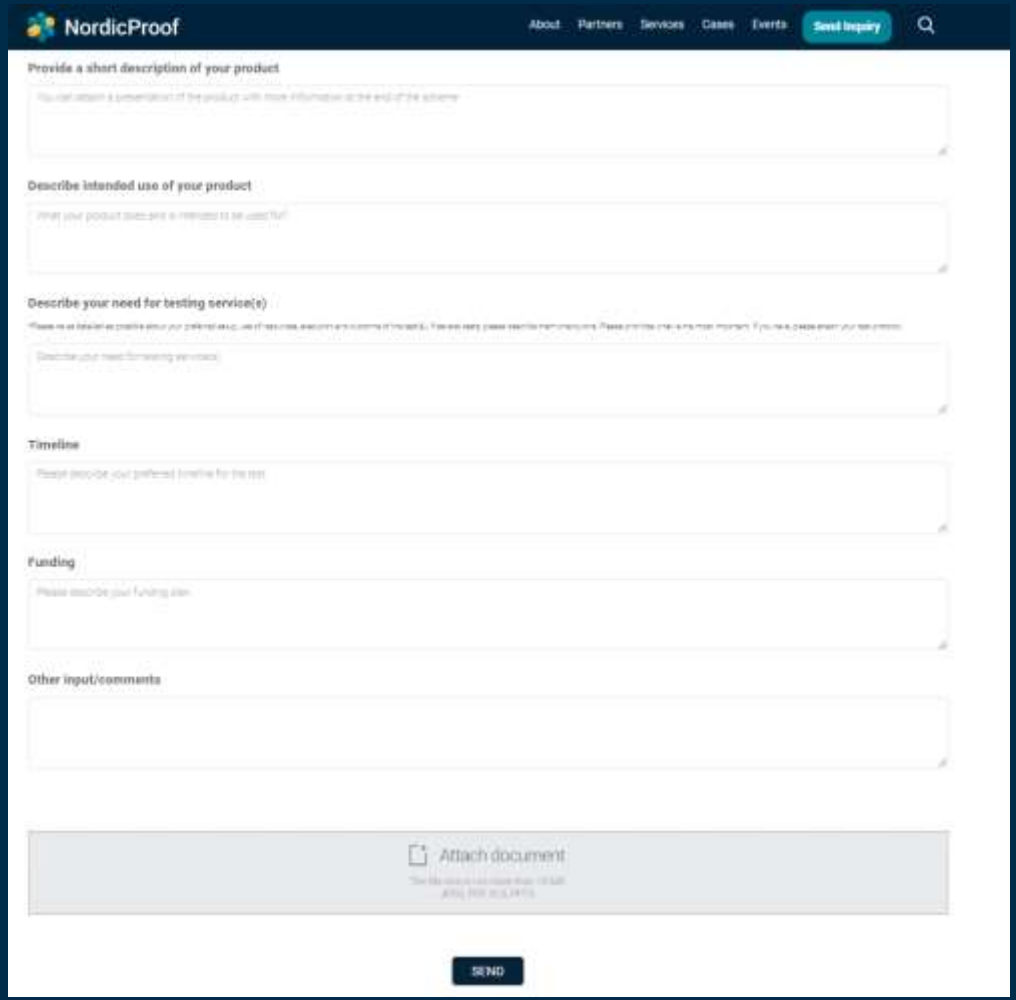

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Available for one-to-one meetings

Nordic Proof test partners:

- OuluHealth Labs, Finland
- HUS Testbed, Finland
- Danderyd Hospital, Sweden
- Nordic Medtest, Sweden
- Sunnaas Hospital, Norway
- Norwegian SmartCare Lab, Norway

Unfortunately the following Nordic Proof partners will not be available for one-to-one:

- VihTek, Denmark
- The Intervention Centre, Oslo University Hospital, Norway

Regulatory experts: Kami Faust and Claudia Dannehl

Nordic Proof Coordinator: Siri Stabel Olsen

Moderator: Bent-Håkon Lauritzen

NordicProof

Welcome to Nordic Proof

www.nordicproof.org

Bridging today’s health solutions with the unlimited potential of tomorrow

Navigating the Regulations for e-Health Companies

Norway Health Tech
Kami Faust, Regulatory Advisor
2 June 2021

Norway Health Tech Academy

- Addressing the increasing need for competence within the regulatory field.
- Focusing on the development of medical device and in-vitro diagnostics, in EU and other relevant markets.
- Building confidence in start-up and scale-up companies through training, both in content and performance.
- Bringing the experts to Norway Health Tech members and others.
- Giving guidance on regulatory matters.

Norway Health Tech Academy
Training and Courses

Norway Health Tech Academy

Organizational strategy	Innovation	Presentation	Digitalization	Regulatory
Company set-up	Business development	Pitch and performance training	Trends and demands	
	Design sprints	Content training		
	IP & Patent			

Norway Health Tech Academy Training and Courses

Norway Health Tech Academy

Organizational strategy	Innovation	Presentation	Digitalization	**Regulatory**
PRRC training	Person Responsible for Regulatory Compliance			
Design control	Design control for medical devices and Project Management			
ISO 13485	Medical devices — Quality management systems — Requirements for regulatory purposes			
ISO 14971	ISO 14971:2019 – Medical devices — Application of risk management to medical devices			
Clinical series	Clinical Evaluation and Investigation Series			
UK Market	Brexit: What changes and how to handle challenges for Norwegian healthcare companies – 3.6			
SaMD	Software as a Medical Device Classification – Clarification of MDR Rule 11 – 10.6			
US FDA	Overview of the US FDA Regulations – End of June			

e-Health Solutions

e-Health is applying digital technology into healthcare practice.

Solutions may range from using the Internet to provide healthcare services to IoT devices and mobile apps.

Examples:

- **Electronic health record** - enabling the communication of patient data between different healthcare professionals
- **ePrescribing** - access to prescribing options, printing prescriptions to patients and sometimes electronic transmission of prescriptions from doctors to pharmacists
- **Telemedicine** - physical and psychological diagnosis and treatments at a distance
- **Telesurgery** - use robots and wireless communication to perform surgery remotely
- **Consumer health informatics** - use of electronic resources on medical topics by healthy individuals or patients
- **m-Health** - use of mobile devices in collecting health data, providing healthcare information, real-time monitoring, and direct provision of care
- **Healthcare information systems** - software solutions for appointment scheduling, patient data management, work schedule management and other administrative tasks surrounding health

Crossing the line from e-Health Solution to Medical Device

- Does your Solution meet the definition of a Medical Device?
- Does your Solution meet the definition of Medical Device Software (MDSW)?
- What is the Intended Purpose of your Solution?
- How do you meet the (EU) 2017/745 Medical Device Regulation (MDR) requirements?
    - Classification
    - Technical Documentation
    - Clinical Evaluation Report

Medical Device – (EU) 2017/745 MDR

Medical Device means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
- providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

The following products shall also be deemed to be medical devices:

- devices for the control or support of conception;
- products specifically intended for the cleaning, disinfection or sterilization of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.

Medical Device Software

Medical Device Software (MDSW) is software that is intended to be used, alone or in combination, for a purpose as specified in the definition of a “medical device” in the medical devices regulation or in vitro diagnostic medical devices regulation.

Reference - MDCG 2019-11 Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR

Intended Purpose

Confirmation, or not, of whether the product being considered fits the definition of a “medical device” and therefore whether or not the regulation applies.

The basis for the classification of the future planned device into one of the four classes of device.

Core text which is needed for the future labelling, instructions, promotional or sales materials, the clinical evaluation and the technical documentation.

“*the use for which a device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements and as specified by the manufacturer in the clinical evaluation*”

Medical Device Classification – MDR Annex VIII

- Rules 1-4 – Non-Invasive Devices
  - Any device which does not penetrate the body through an orifice or the surface of the body.
- Rules 5-8 – Invasive Devices
  - Any device which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body
- Rules 9- 13 – Active Devices
  - Any device whose operation depends on a source of energy other than that generated by the human body for that purpose, or by gravity, and which acts by changing the density of or converting that energy
- Rules 14-22 – Special Rules

Classes of Medical Device

- Class I (low risk)
- Class Is - delivered sterile
- Class Im - measuring function
- Class Ir - reprocessed
- Class IIa (medium risk)
- Class IIb (medium/high risk)
- Class III (high risk)

Technical Documentation Requirements

Technical Documentation is a compilation of all relevant documents for a product which gives the evidence that a medical device meets the **general safety and performance requirements** (GSPRs) of the MDR.

No matter the class of the medical device technical documentation must always be available and maintained throughout the lifecycle of the device.

General Safety and Performance Requirements

Devices shall achieve the performance intended by their manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose. *They shall be safe and effective and shall not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art.*

Clinical Evaluation Report

Clinical Evaluation *is a systematic and planned process to continuously generate, collect, analyse and assess the clinical data pertaining to a device in order to verify the safety and performance, including clinical benefits, of the device when used as intended by the manufacturer.*

Clinical Data *is Information concerning safety or performance that is generated from the use of a device and is sourced from the following:*

- *clinical investigation(s) of the device concerned,*
- *clinical investigation(s) or other studies reported in scientific literature, of a device for which equivalence to the device in question can be demonstrated,*
- *reports published in peer reviewed scientific literature on other clinical experience of either the device in question or a device for which equivalence to the device in question can be demonstrated,*
- *clinically relevant information coming from post-market surveillance, in particular the post-market clinical follow-up*

Clinical Investigation *is any systematic investigation involving one or more human subjects, undertaken to assess the safety or performance of a device.*

Norway Health Tech

We at Norway Health Tech are here to help so please feel free to reach out with any questions.

And don't forget to register for our June 10th round table discussion on Software as a Medical Device Classification - Clarification of MDR Rule 11

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Lauren Willgeroth
Claudia Dannehl

LINK Medical GmbH, Berlin

Clinical Evaluation for Software as a Medical Device (SaMD)

June, 2nd 2021

Presentation reflects current knowledge and own opinion of the authors.
No guarantee for correctness of any of the provided information.
Any liability is excluded.

Who we are: LINK Medical

- Clinical Research Organisation in Northern Europe
- Founded in 1995
- 190 employees
- Full-service for Clinical Studies in Pharma, Medical Device & Combination Products

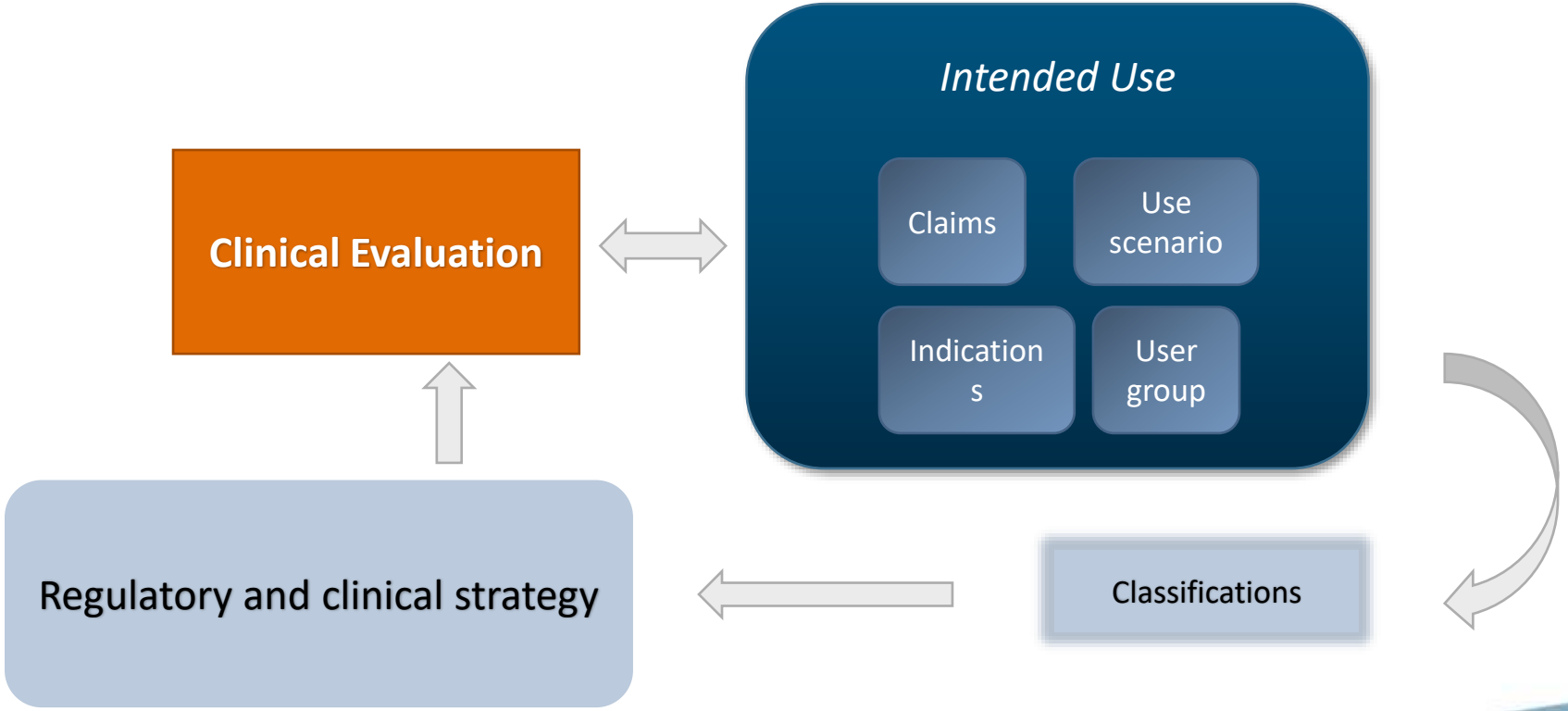
Provided services for medtech/digital health:
- Ad-hoc consultancy
- Deep-dive feasibility assessments for planned business (regulatory/market access/reimbursement)
- Target Product Profile or training workshops
- Outsourced regulatory/quality related tasks

Who we are: Medical Devices Germany

Dr. Claudia Dannehl

Claudia.Dannehl@linkmedical.eu

Consequences



Clinical Evidence Reading Assignments

- Medical Device Regulation EU/2017/745 (MDR)
- MDCG 2020-5 Guidance on Clinical Evaluation – Equivalence
- MDCG 2020-1 Guidance Clinical Evaluation Software and IVDR
- IMDRF MDCE WG/N55FINAL:2019 - Clinical Evidence - Key Definitions and Concepts
- IMDRF MDCE WG/N56FINAL:2019 - Clinical Evaluation
- IMDRF MDCE WG/N57FINAL:2019 - Clinical Investigation
- IMDRF/SaMD WG/N41FINAL:2017 - Software as a Medical Device (SaMD): Clinical Evaluation
- MEDDEV 2.7.1/Rev 4 – Clinical evaluation: a guide for manufacturers and notified bodies under Directives 93/42/EEC and 90/385/EEC
- ISO 14155 Clinical investigation of medical devices for human subjects -- Good clinical practice

… and more for Legacy Devices, PMCF

MDR/IVDR: Responsibility fo clinical planning

Clinical data and CLINICAL EVALUATION* results [...] of a sufficient amount and quality to allow a qualified assessment of whether the device is safe and achieves the intended CLINICAL BENEFIT(S), when used as intended [...]

(Art. 2 (51) *MDR / Art. 2 (36) IVDR)*

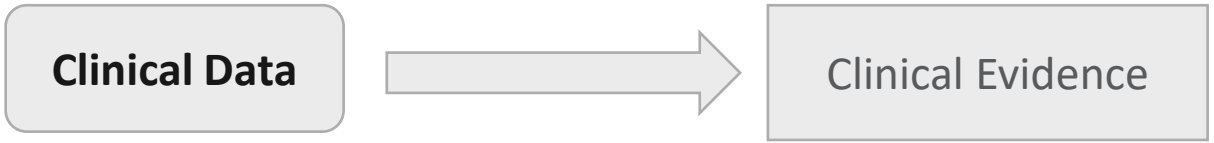
** syn. PERFORMANCE EVALUATION for IVDs*

The manufacturer shall specify and justify the level of CLINICAL EVIDENCE neccessary to demonstrate conformity with the relevant GSPR. That level of CLINICAL EVIDENCE shall be appropriate in view of the characteristics of the device and its intended purpose

(Art. 61 (1) MDR/ Art. 56 (1) IVDR)

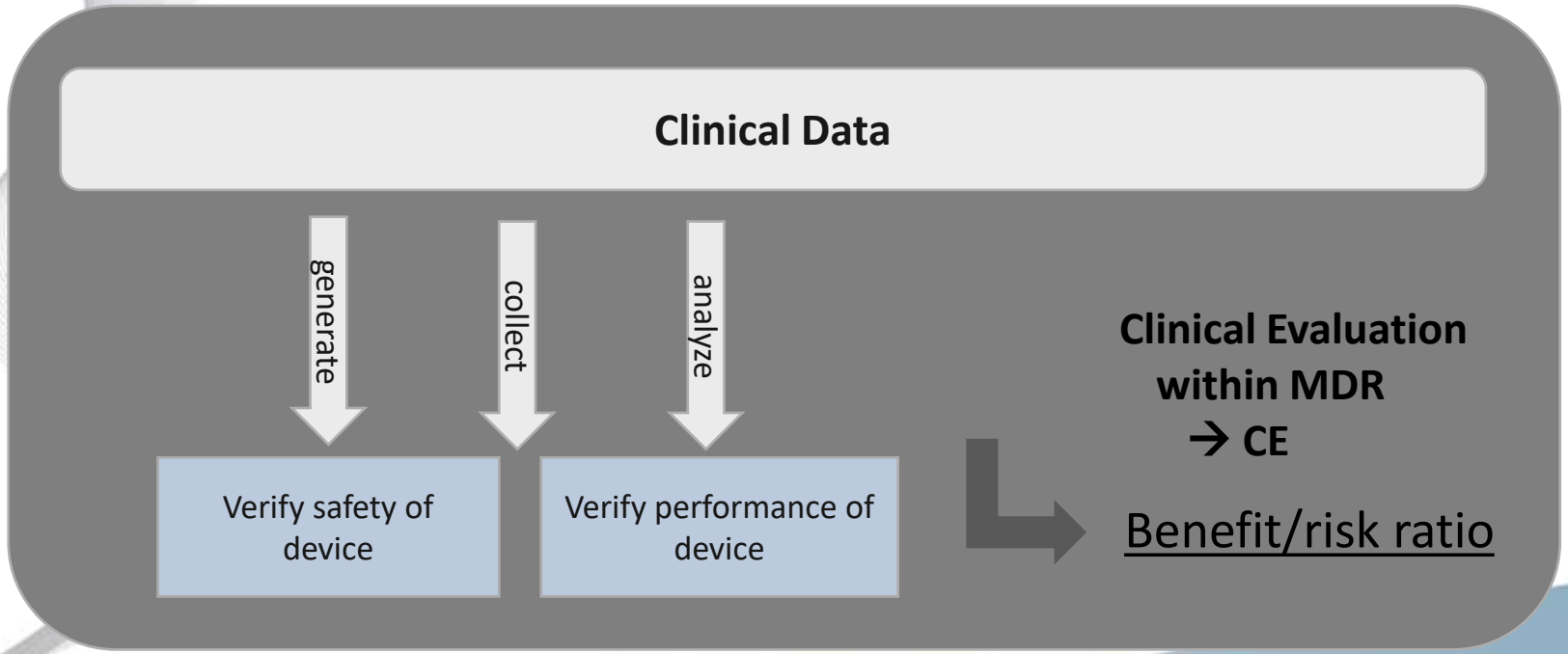
Clinical Evidence

- Real clinical context
- Clinical risks
- Benefit for the patient



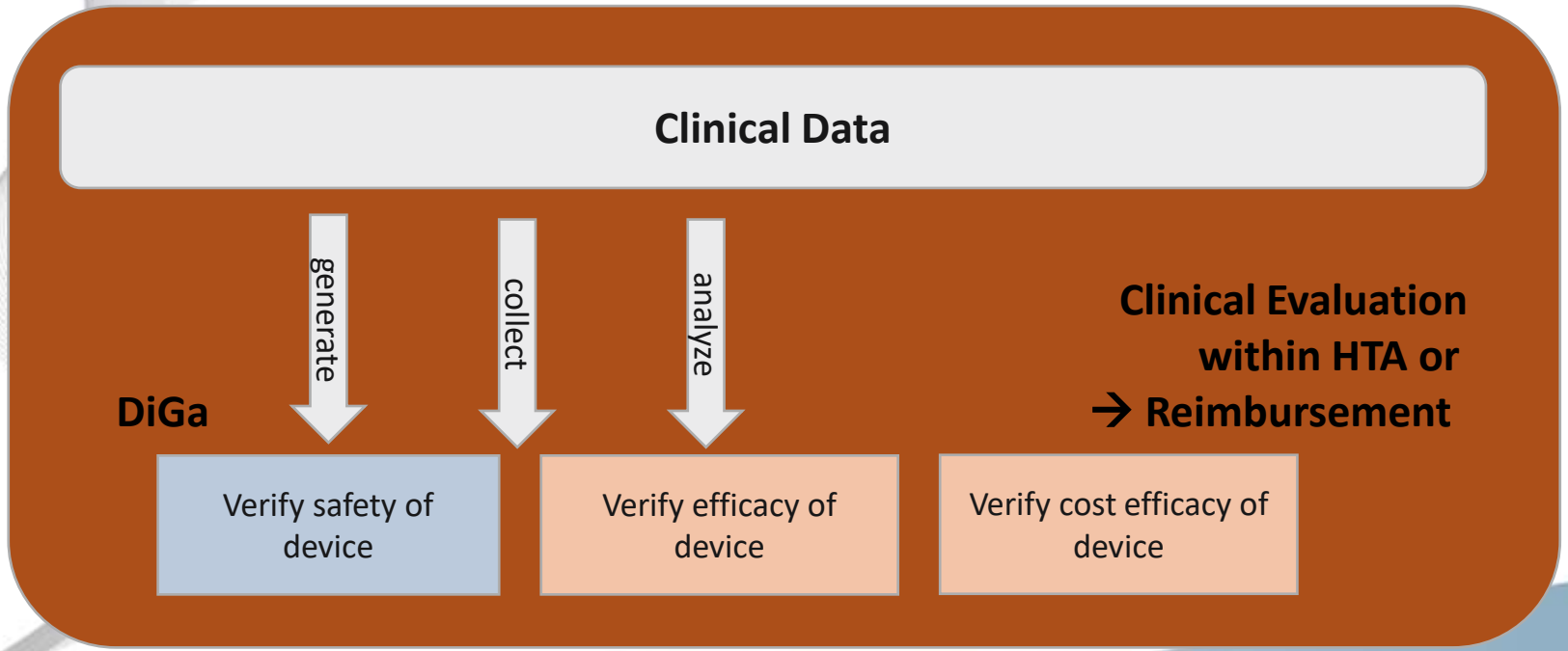
Definitions

Mandatory for ALL medical devices!

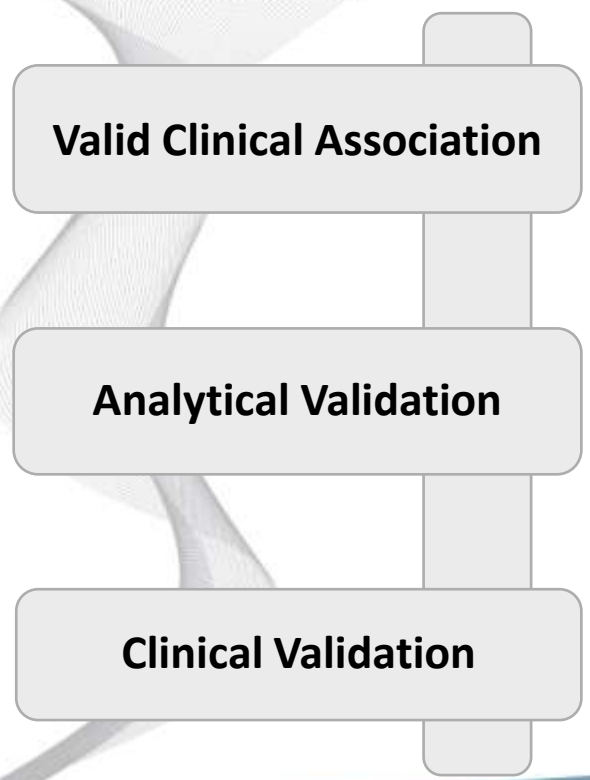


Definitions

NOT mandatory for medical devices!



Clinical Evaluation with CE Conformity Assessment



Valid clinical association between software output and targeted clinical outcome?

Does software correctly process input data to generate accurate, reliable, and precise output data?

Does use of software output data achieve your intended purpose in your target population in the context of clinical care?

Clinical Evaluation with CE Conformity Assessment

Valid Clinical Association

Existing evidence:

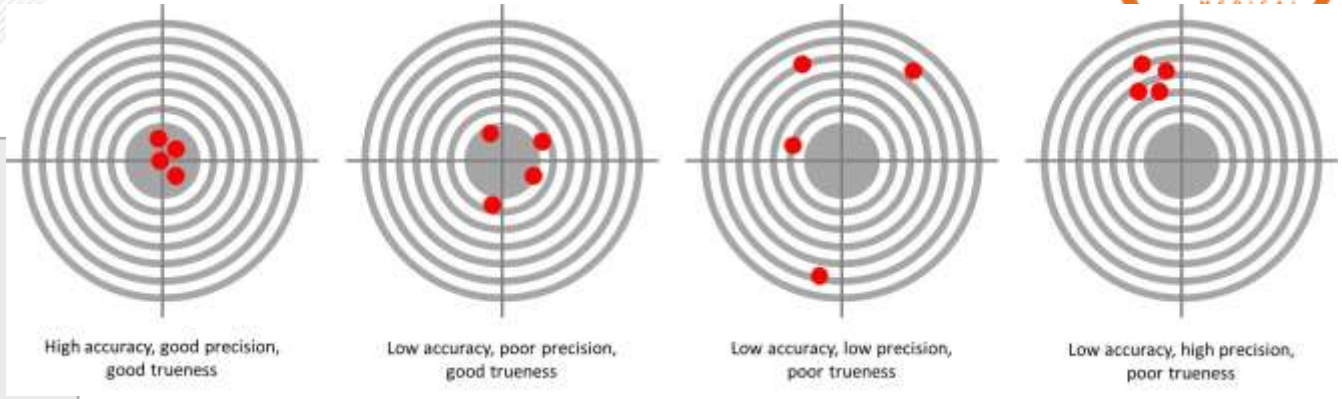
- Literature searches,
- Original clinical research
- Professional society guidelines

New evidence:

- Secondary data analysis
- Perform clinical trials

→ *state of the art*

Clinical Evaluation with CE Conformity Assessment



Analytical Validation

Verification and Validation activities:
(a) Does your software meets its specifications?
(b) Do specifications conform to user needs and intended uses?

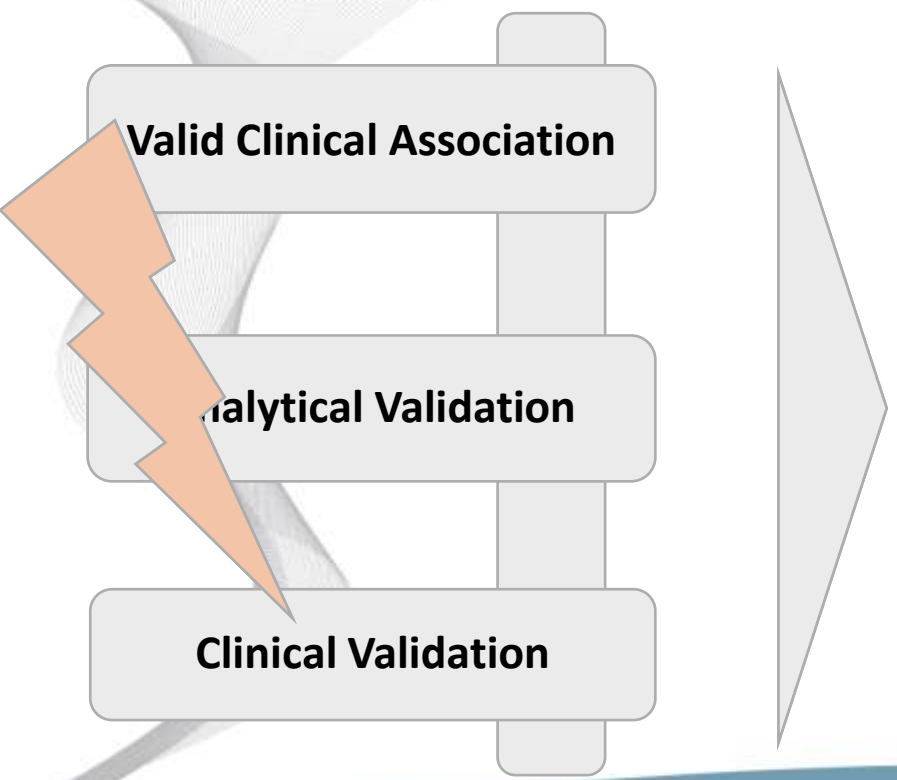
Note: IVD requirements might be relevant

Clinical Evaluation with CE Conformity Assessment

Clinical Validation

Address:
Intended use, target population
User can achieve results!

Clinical Evaluation with CE Conformity Assessment



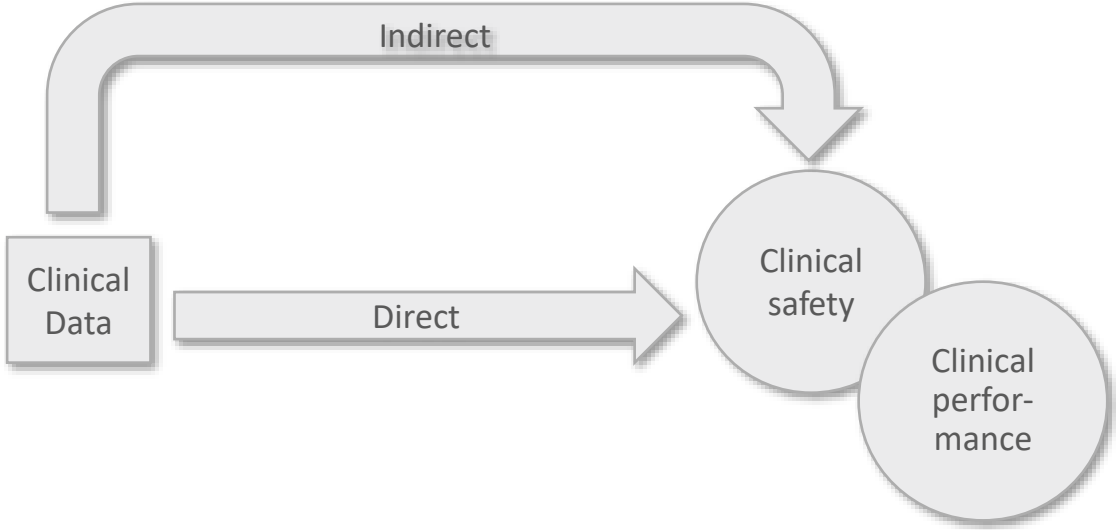
- Perform ongoing data analysis
- Modify intended use to one that can be supported by available evidence
- Modify the target clinical association
- Make changes to software

Definitions

Clinical Data

How and where can we get them?

Definitions



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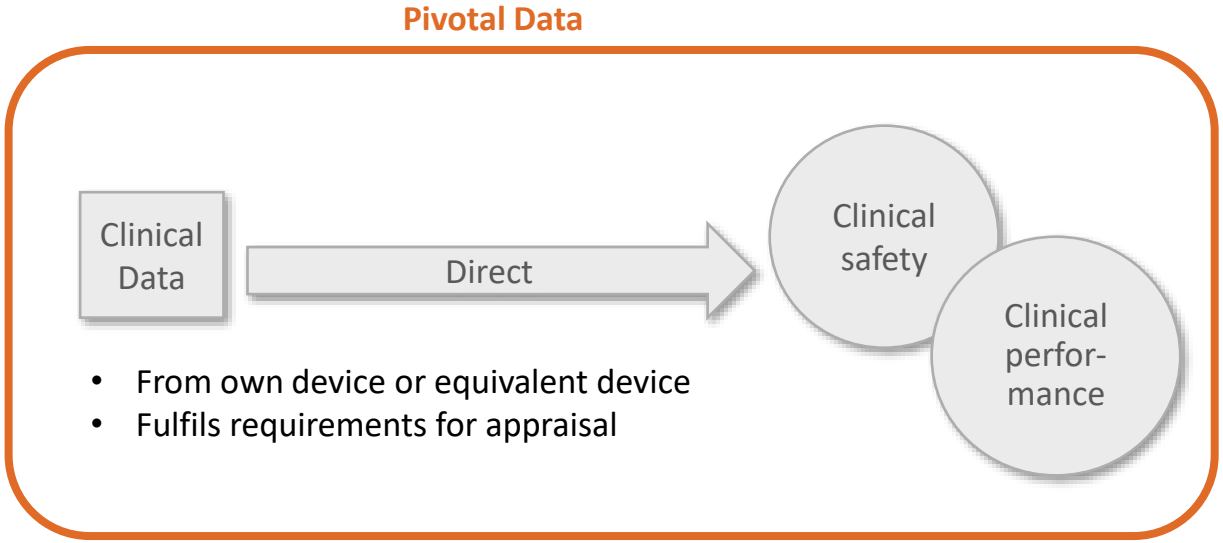
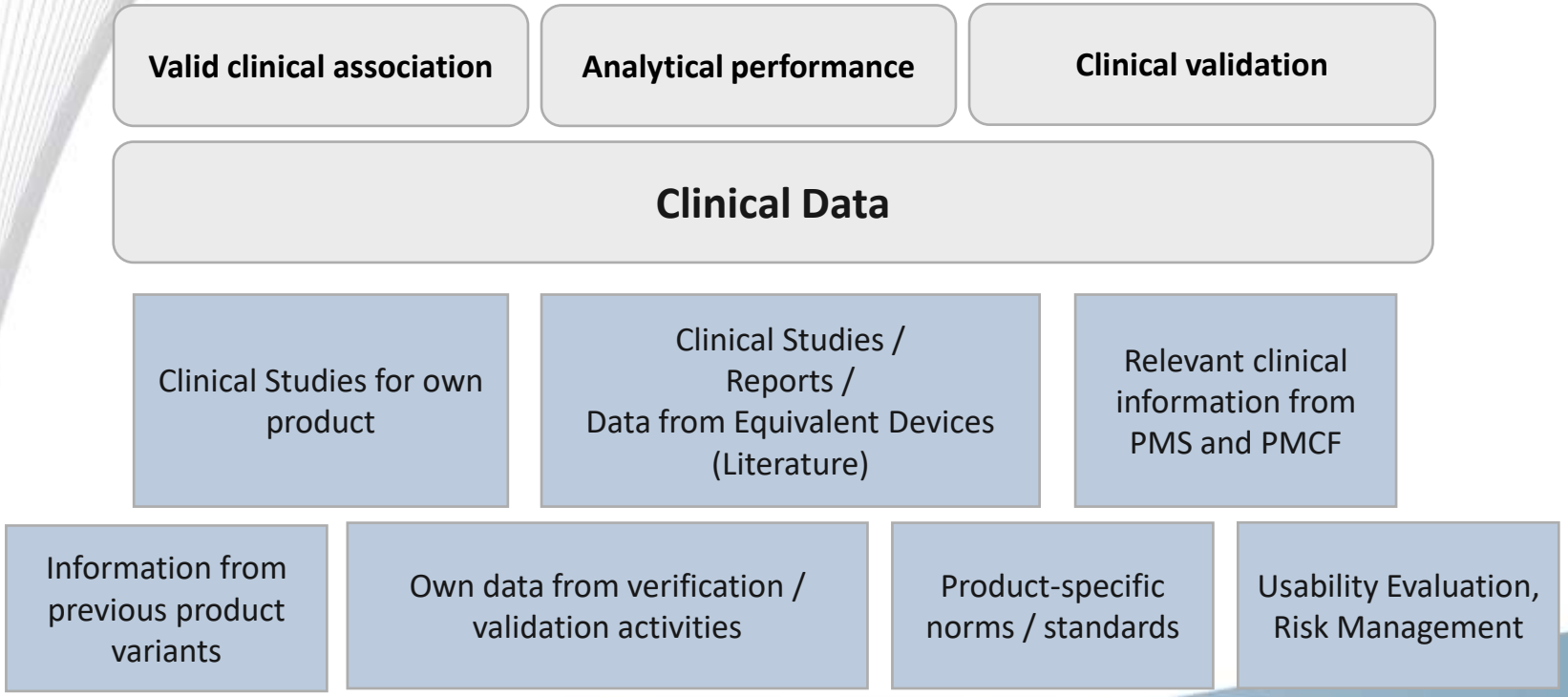


Clinical Data



Clinical Data

Valid clinical associatio

ion

Clinical Studies for ow product

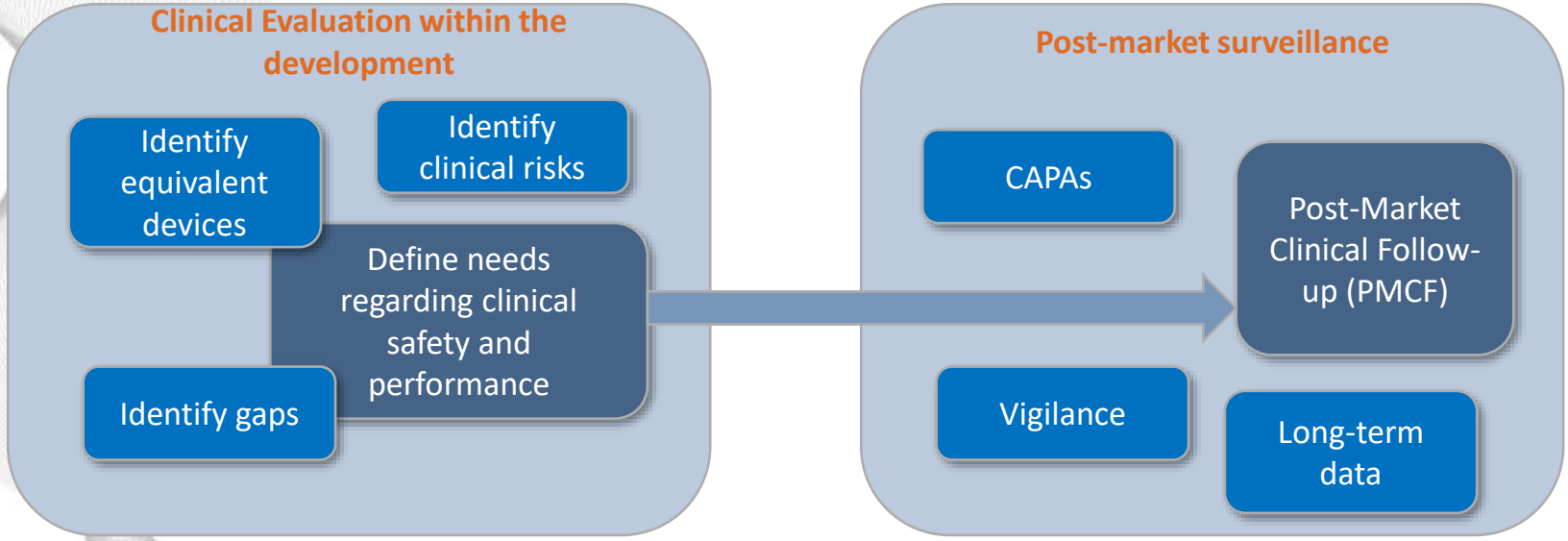
nical from MCF

Information from previous product variants

Own

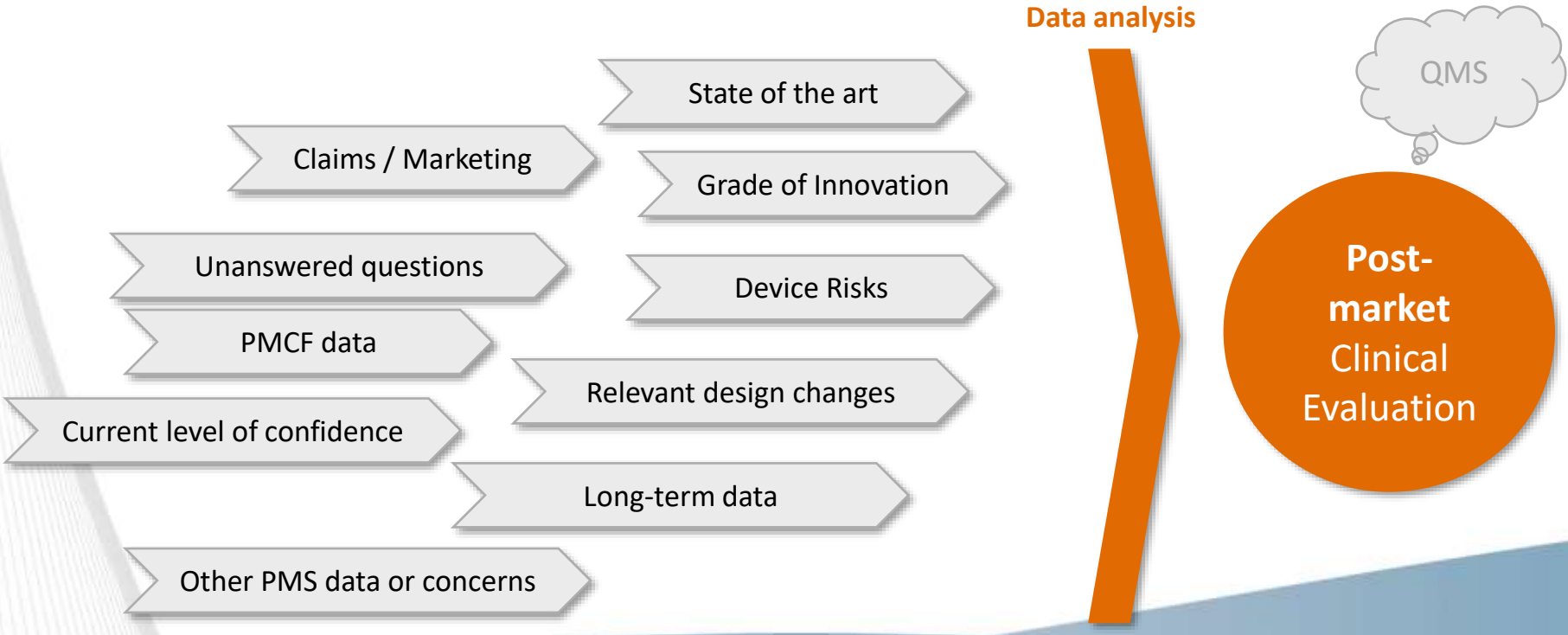
Usability File, Risk Management

Clinical Evaluation: data sources

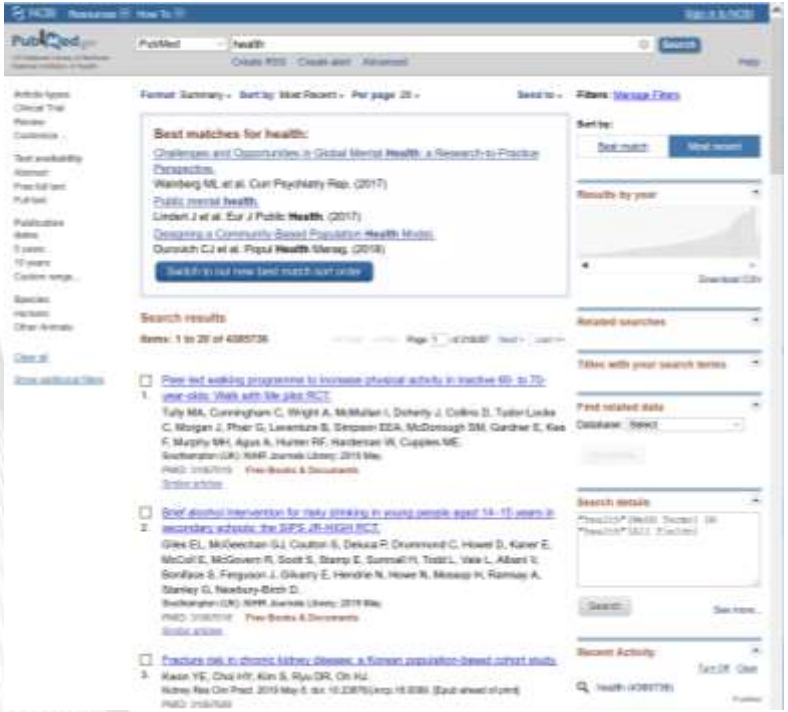


Rule: the shorter the product innovation is on the market,
the more effort has to be spent during post-market surveillance

Clinical Evaluation: data sources



Literature Searches



Validity of data? Bias?

Search algorithm?

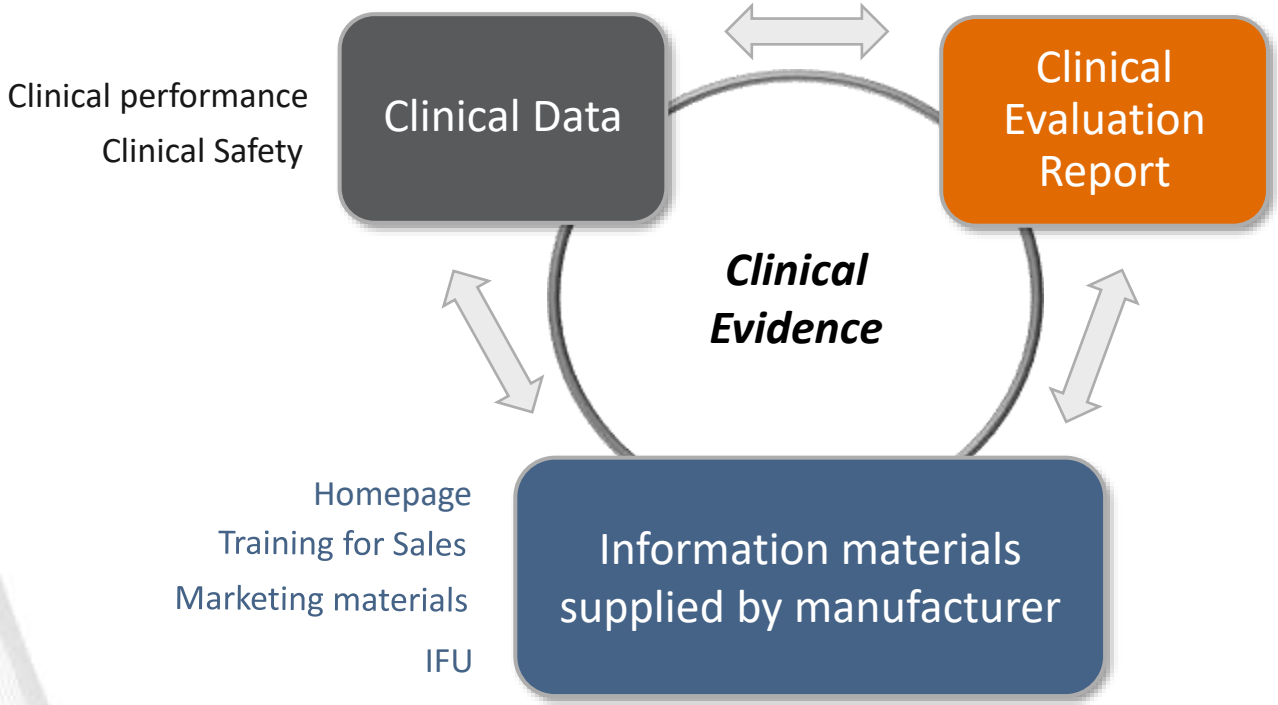
Appropriate databases?

Equivalence?

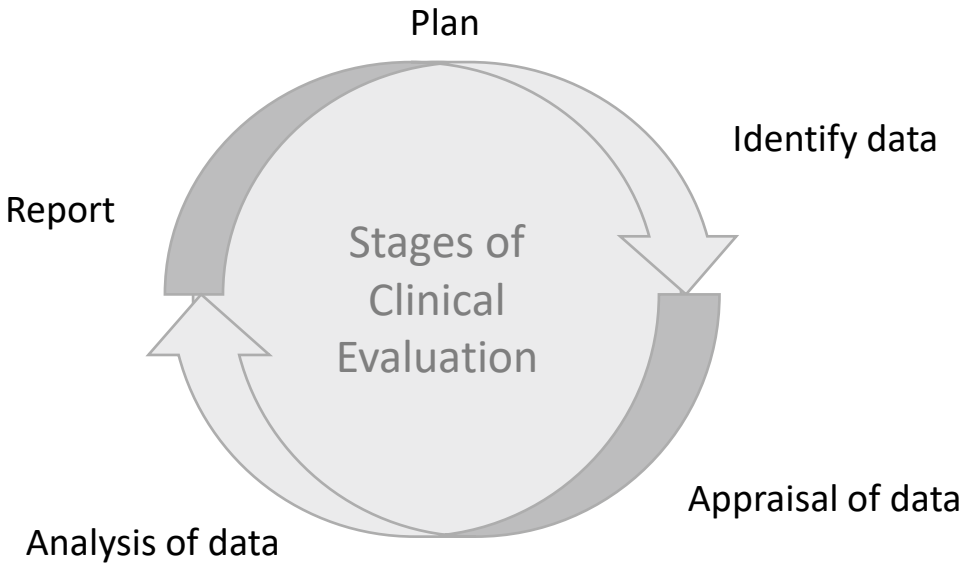
Requirements to authors…

MEDDEV 2.7.1. Rev. 4

Clinical Evaluation: goal

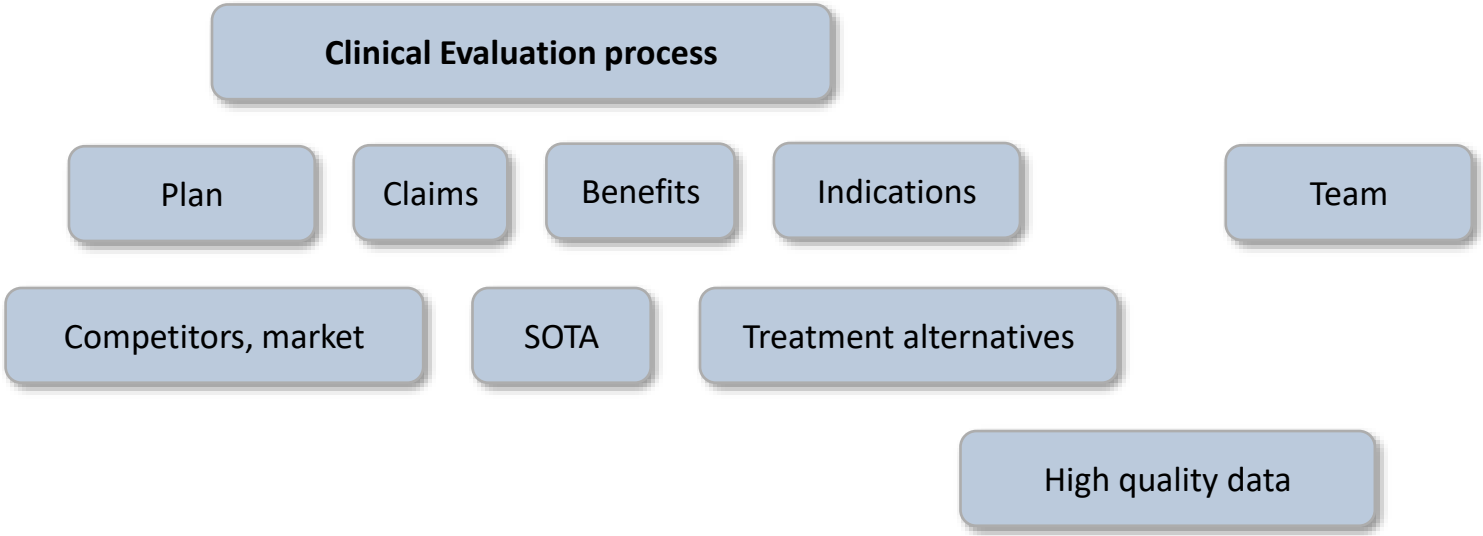


Clinical Evaluation within CE Conformity Assessment

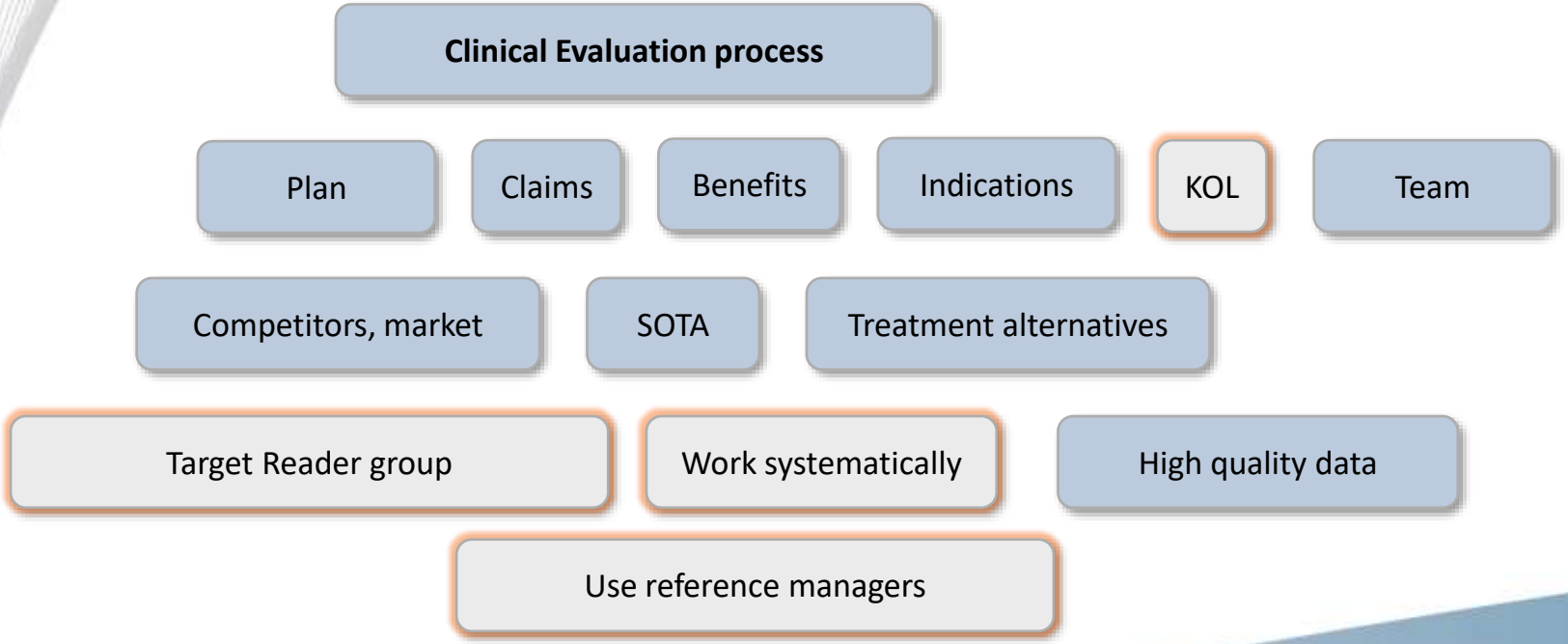


MEDDEV 2.7.1 Rev. 4

Clinical Evalution Hacks

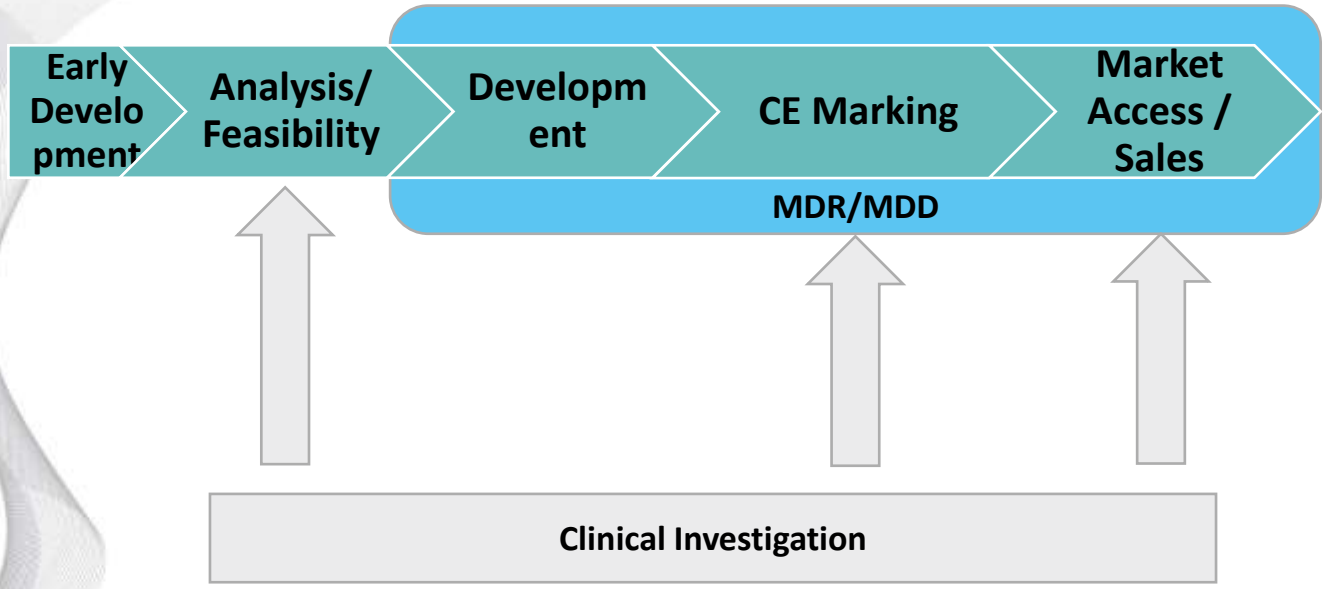


Clinical Evalution Hacks



Clinical Investigations in Humans

Clinical Investigations: Study types

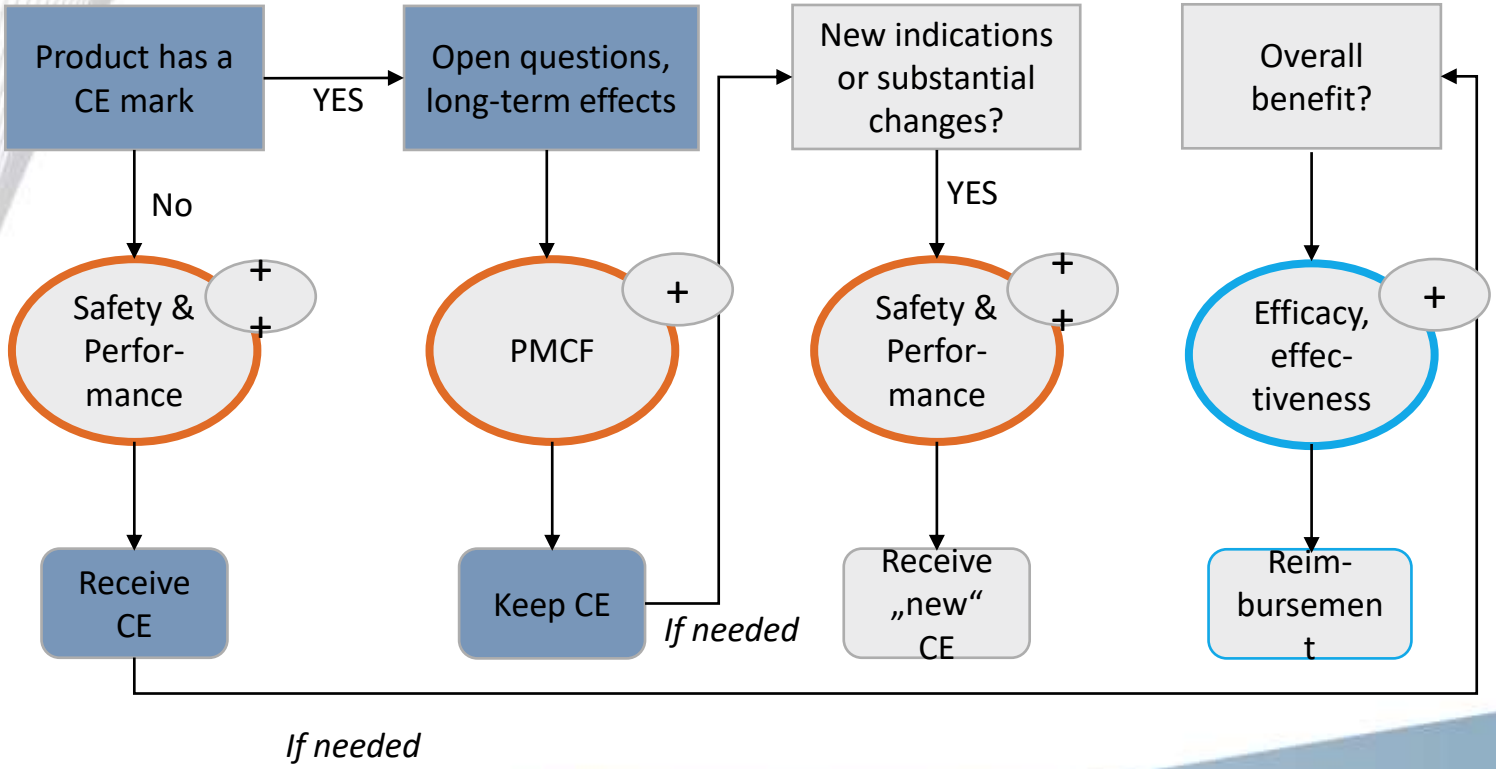


Clinical Investigations: Study Types

- **Interventional studies**
  - Follows study protocol -> standardized, „artificial“ data
  - Patients treated „outside“ standard of care with non-CE marked device
  - Example: Safety and performance, Efficacy, Effectiveness
  - Need approval by Regulatory Authority and Ethics Committe

- **Non-Interventional studies**
  - Follows clinical routine -> Real World Data
  - Patients treated „inside“ standard of care with CE-marked device
  - Example: PMCF, Efficacy, Effectiveness
  - Need approval by Ethics Committee (study start needs to be notified to Regulatory Authorities and health insurer associations)

Clinical Investigations: Study types



Clinical Investigation: Study Design

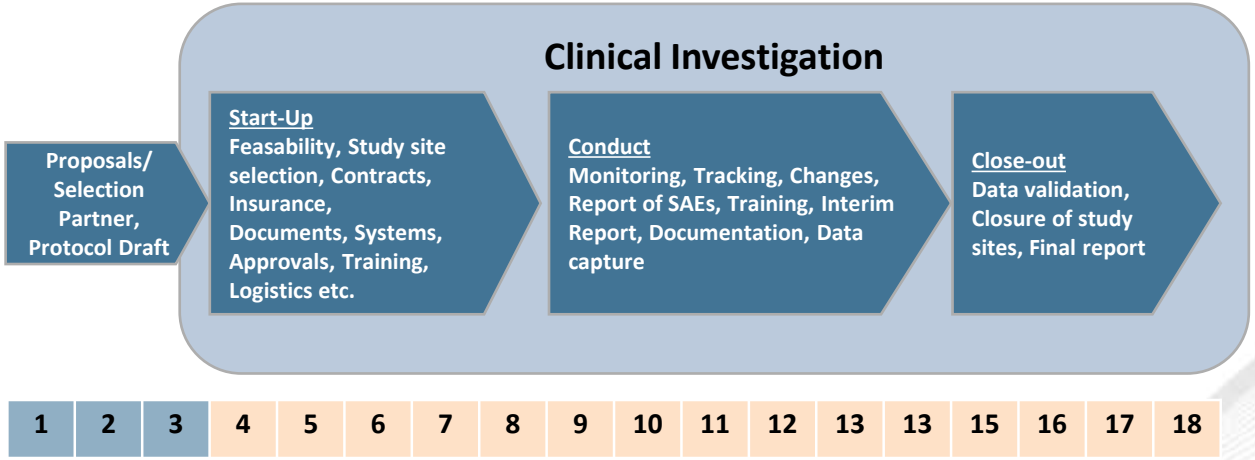
- Sponsor initiated; Investigator initiated
- Interventional, Non-Interventional
- Monocentric, Multicentric
- National, International
- Controlled
  - Randomized
  - Open
  - Single Blind, Double Blind
  - Parallel group
  - Cross over
- Comparator
  - Sham-Device, Sham-Procedure, etc. => Placebo
  - Other Medical Device

- **Randomized Controlled Trial**

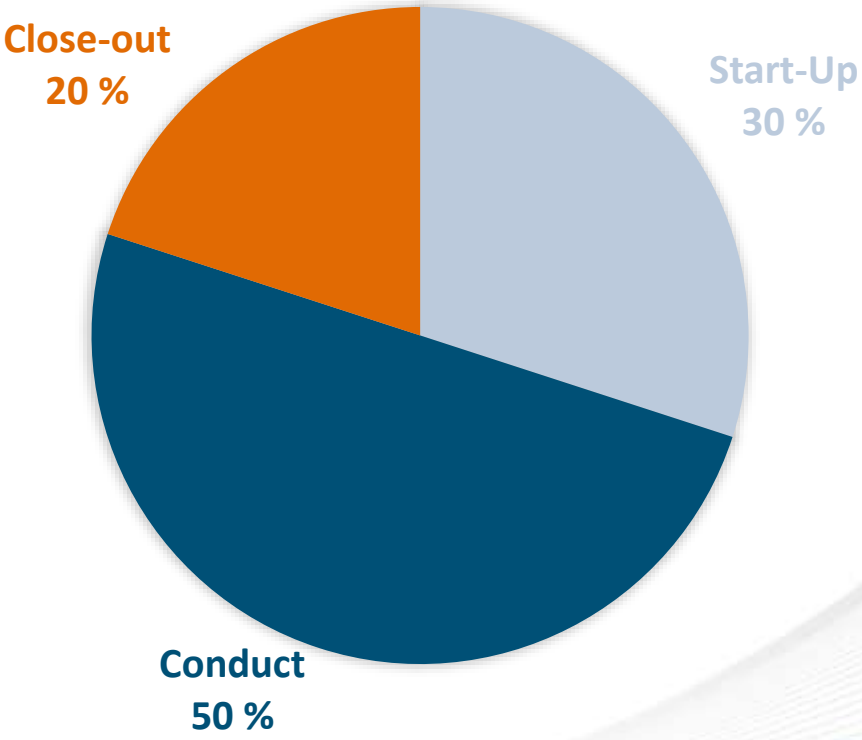
Clinical Investigation: Medical Device vs. Pharma

Medicinal product 	**Phase I** Small study (20-100; healthy or with condition) to determine preliminary safety and dosage	**Phase II** Larger study (200-500 with condition) to determine efficacy and adverse effects	**Phase III (Pivotal)** Big study (600-1000 with condition) to determine efficacy and monitor adverse effects	**Phase IV** Post-marketing study to collect long-term data
Medical Device 	**Pilot** Small study (10-30) to determine preliminary safety and performance	**Pivotal** Larger study (150-300) to determine safety and performance		**PMCF** Long-term data, unanswered questions

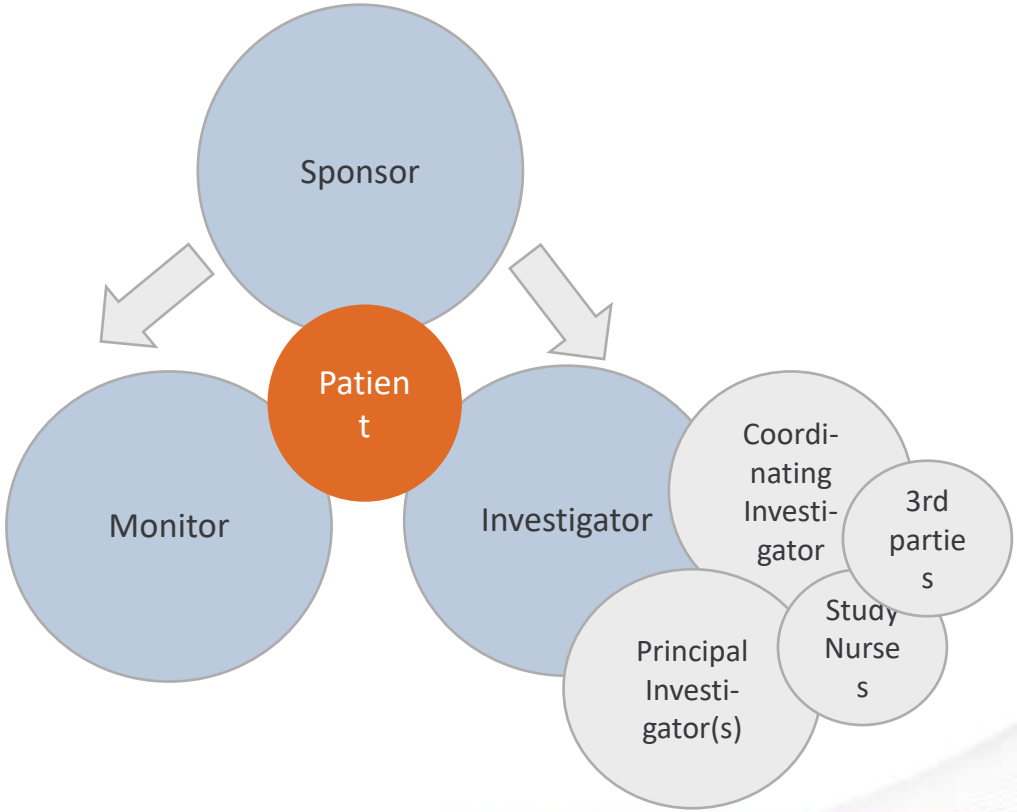
Clinical Investigations: Phases



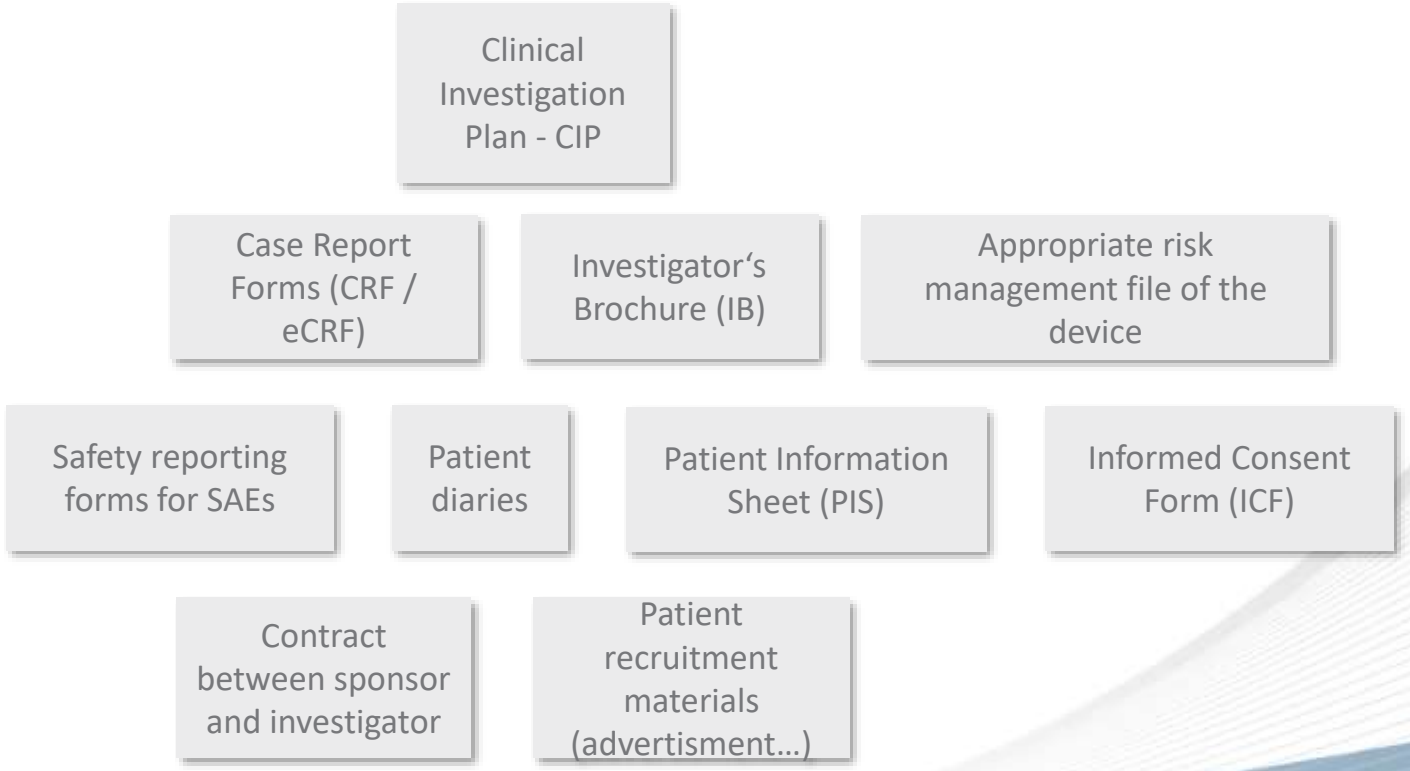
Cost distribution per phase



Clinical Investigations: Main Involved Parties



Start-up: Key documents for EC/RA Approval



Clinical Evaluation for SaMD

03.06.2021

Claudia Dannehl
Claudia.Dannehl@linkmedical.eu

Agenda

12:00 pm	Welcome and short intro to Nordic Proof and the program *Siri Stabel Olsen, Coordinator Nordic Proof*
12:10 pm	Navigating the regulations for e-Health companies. *Kami Faust, Regulatory Advisor at Norway Health Tech*
12:25 pm	Clinical Evaluation for Software as a medical device *Claudia Dannehl, Medical Device Manager at Link*
12:45 pm	An e-Health companies' journey from concept to submission *Anders Aune, CEO at Picterus*
1:00 pm	Closing of webinar. One2One meetings in separate online meeting rooms
3:00 pm	End program

NordicProof

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eHealth solutions
with global impact

Anders Aune, CEO

Picterus AS


140+ million babies are born every year
60 – 80% of these will get jaundice
100,000 deaths
175,000 babies with brain damage
Jaundice is the number one reason for hospital readmission after birth in high income countries
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Current solutions

Blood sample

Transcutaneous reader

Accurate but expensive

Visual inspection

Cheap but unreliable

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The Picterus app

State-of-the-art bio-optics
Physics based simulations
Color calibration card & app

Easy-to-use
Used in any setting

Immediate results
High accuracy

Affordable

Available

Accurate

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Picterus screening tool

System of 3 components:

Smartphone application	Image analysis on server	Color calibration card

Intended use:

- Screening tool – not diagnosis
- 1st version for health care workers
- Assist in jaundice assessment
- Skin type and phone limitations

Later versions:

- Parents as users
- All skin types
- “All” phones
- New markets

picterus

Relevant risks – clinical evaluation

POTENTIAL HAZARD	FORESEEABLE SEQUENCE OF EVENTES	HAZARDOUS SITUATION AND HARM	RISK MITIGATION
Transcutaneous levels of bilirubin are not correlated to serum levels	Serum bilirubin levels cannot be detected on skin surface	Detection of jaundice might be false negative and therefore misdiagnose	Perform clinical literature search
Bilirubin estimates obtained from digital images are not correlated to serum levels	Serum bilirubin levels cannot be detected by digital imaging	Detection of jaundice might be false negative and therefore misdiagnose	Perform clinical literature search
Picterusestimates are not correlated to serum levels	Serum bilirubin levels cannot be detected by Picterus	Detection of jaundice might be false negative and therefore misdiagnose	**Perform clinical studies**

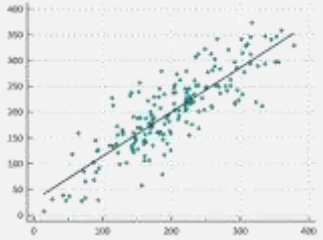
Clinical studies

- Patient group: Term born, normal birth weight with and without jaundice
- Bilirubin in blood sample (gold standard) compared to estimates from Picterus app

Norway:

› St.Olav and Ahus

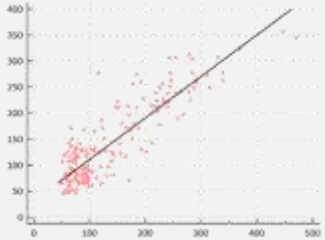
› 301 newborns



Mexico:

› Irapuato

› 166 newborns



	Norway	Mexico
Correlation (Pearson)	0.84	0.87
Standard error of estimate	43 umol/l	43 umol/l
Sensitivity (Severe jaundice)	100%	90 %
Specificity (Severe jaundice)	67%	90 %

Extensive data-base of clinical data collected: Norway, Mexico, Nepal, Indonesia and Uganda.

1400+ data sets of newborns

Enabling AI improvements of system

picterus

Our Journey

Company

- Idea 2012
- Master thesis 2014
- Company founded 2015
- 1st Clinical study 2017
  - AA PhD 2016
- Study Mexico
  - Student thesis
- EIC Accelerator grant
- 12 full-time employees
- QA/RA manager 2021

Regulatory

- QMS ISO13485 certified 2019
- Classification issue MDD
  - Class 1 or Class 1m
- Classification MDR
  - IIa
  - Calibration card class I
- Technical file submitted April 1st
  - CE mark Sept/Oct?

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Thank you for your attention!

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