Launching of the BIC Guide

A support tool for commercialisation of your biomarker invention

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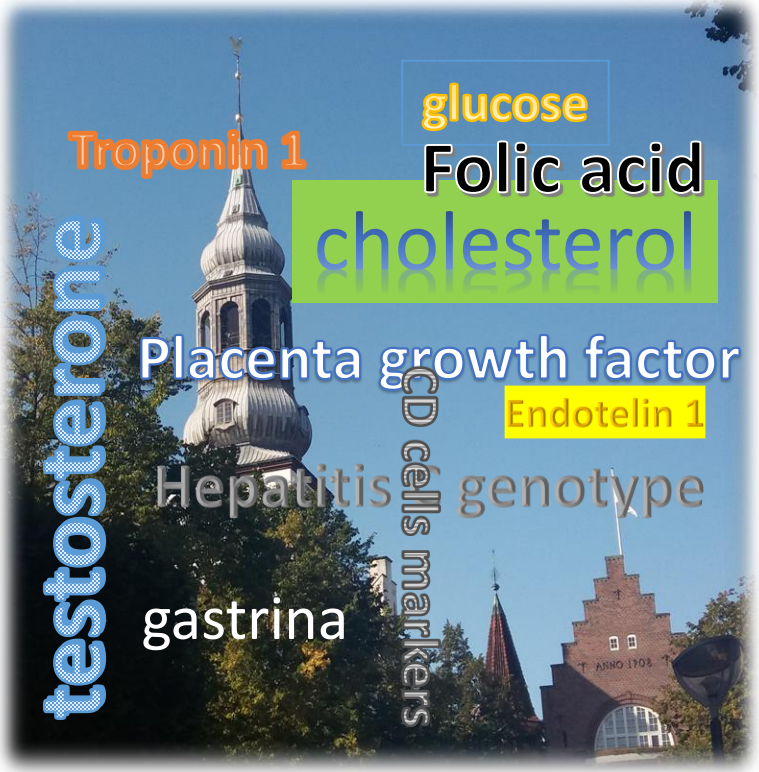
Agenda

1. Biomarker definition
2. Biomarker invention and its applications
3. Commercialization of Biomarkers
4. The BiC Guide – Demonstration

   - 5-10 mnshort break

   for looking at the BIC Guide
5. A Case story
6. Discussion and feedback



1. Biomarker definition

Specimen + quantification + context

- Any substance, structure, or process that can be measured in the body or its products and influence or predict the incidence or outcome or disease (*WHO, 2006).*

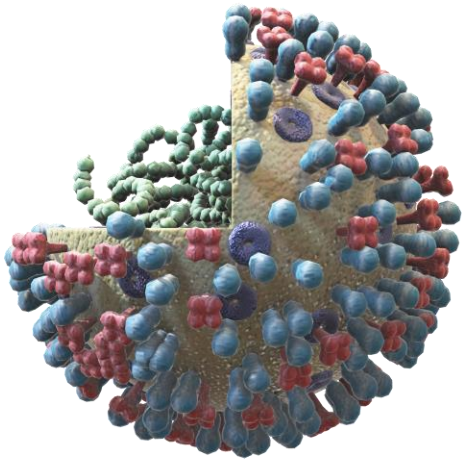
- A biological molecule found in blood, other body fluids, or tissues that can be used to follow body processes and diseases in humans and animals *(European Medicines Agency).*

- A defined characteristic that is measured as an indicator of normal biological processes, pathogenic processes or responses to an exposure or intervention *(FDA-NIH Biomarker working group, 2017).*

2. Biomarker invention

What is a biomarker invention?

(in the context of the BIC Gide)



- Is the **discovery** of a molecule that can be used as an indicator of body processes both in health and disease and that is available to serve a purpose mainly in:
  - ✓ diagnostics
  - ✓ drug discovery & development
  - ✓ personalized medicine
  - ✓ disease risk assessment
  - ✓ other applications (DNA fingerprinting, ecotoxicology, and forensics).

From invention to a product

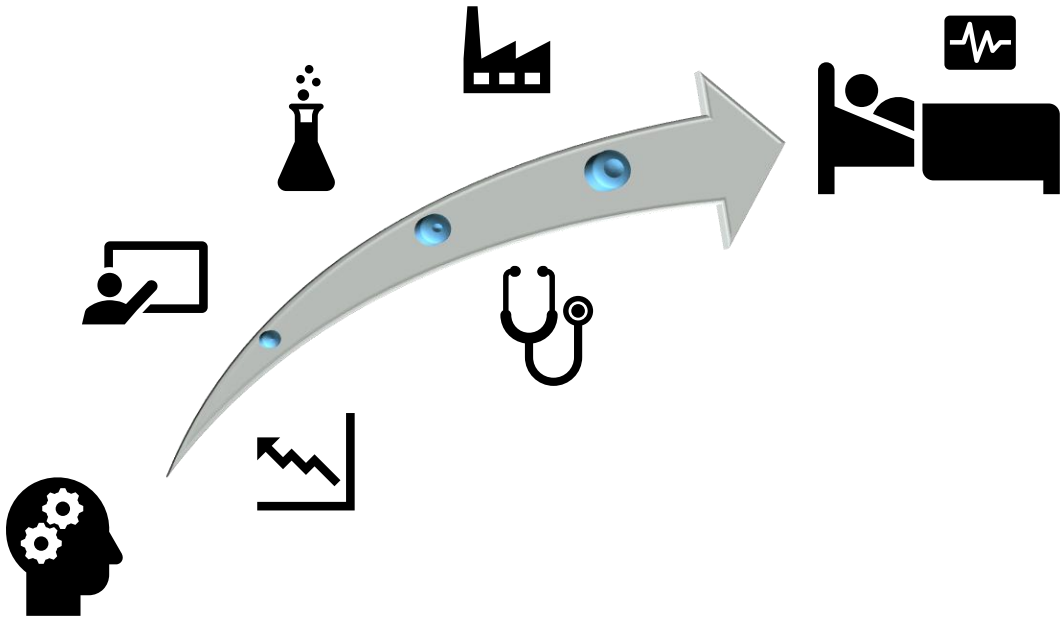
- What can the biomarker **be used for** ?
- How to have a **structured process** to evaluate them in an objective way?
- How to **validate** to make the biomarker a reliable diagnostic tool ?
- Which **clinical setting** should it be transfer to?
- What is the invention can be **commercialised**?

Issues to take into consideration while evaluating

- Is the invention based on a single marker or multiple markers?
- When a multiple marker, how to deal when the ratio between those different markers is the key to the diagnostic.
- How to choose the right technological solution to fit a diagnostic.
- How to come to a diagnostic that is relatively cheap, quick, reliable (if that is the main criteria for success for commercialisation)… and that answer to the regulatory obligations
- Is there existing technology platform to transfer the application to?
- Which alternative technologies can be used?

3. Commercialisation of Biomarkers

Actors in a commercialization process



- Researcher team
- Technology transfers offices
- Innovation centers
- Industrial partners
- Laboratories
- Health system
- **Patients**

Why commercialize a biomarker?

- Research results will most of the time never reach **the benefit of the patient** unless they go through a commercial route.

- Increased complexity for the regulation for medical devices and IVD .

- Goal is to provide patients new IVD tests that will:
  - Provide better or earlier diagnostic
  - Predict the risk for development of certain conditions
  - Prognose the development of a disease
  - Or monitor the effect of a treatment

Questions to adress as a TTO

- General value in the clinical context
- What is the problem your invention is able to solve, that can be told by the biomarker and its mechanism.
- Clinical care pathway.
- Help the inventor to convince other of the value created on the different parameters (Technical, clinical, economics, patients outcome etc..)
- How to work with technologies that are not too expensive and then kill the business case. We need to ensure the commercial viability.

Communication is the key in many of the collaboration issues

- Communication between scientist and people from the industry
- Dialogue and collaboration between the TTO officer and the scientist - understanding of each expertise
  - expectations and roles to be clearly defined.
- The BIC Guide gives a **better visualisation** of the cross disciplinary approach that is key for successful commercialisation and that all parties can relate to
- We started to look at the perspective from different users (Scientist, TTO officer, industry etc..) and decided to focus on the journey itself instead.

Why the BiC Guide?

- To create an **overview** of the process behind the journey **from discovery to commercialisation.**

- To help the users (usually a team comprising at least the scientists and the TTO) to build their own path on how to transform a biomarker fundings into an IVD assay and a measurable product.

- To support the maturing process of the commercialisation route.

  The results of your research is not enough. You will most often need to transfer research results into something more routinely approved in a clinical laboratory.

- Technology transfer from research institution context

  Fields are broad (orthopaedics, biochemistry, radiology, etc…)

  Diversity of the nature of medical devices (Invasive, non invasive, digital solutions etc…)s

What is the BiC Guide?

- **A supporting tool** for evaluation, development and validation of a biomarkers invention into a commercial product

- IT IS NOT RELEVANT if you do not believe in a commercial value for your biomarker invention or do not intend to go for commercialisation.

- It will not tell you what to do or not to do

- It will support you in the process of taking the decisions that are relevant for your own project, supporting your own internal procedures and structure your project management.

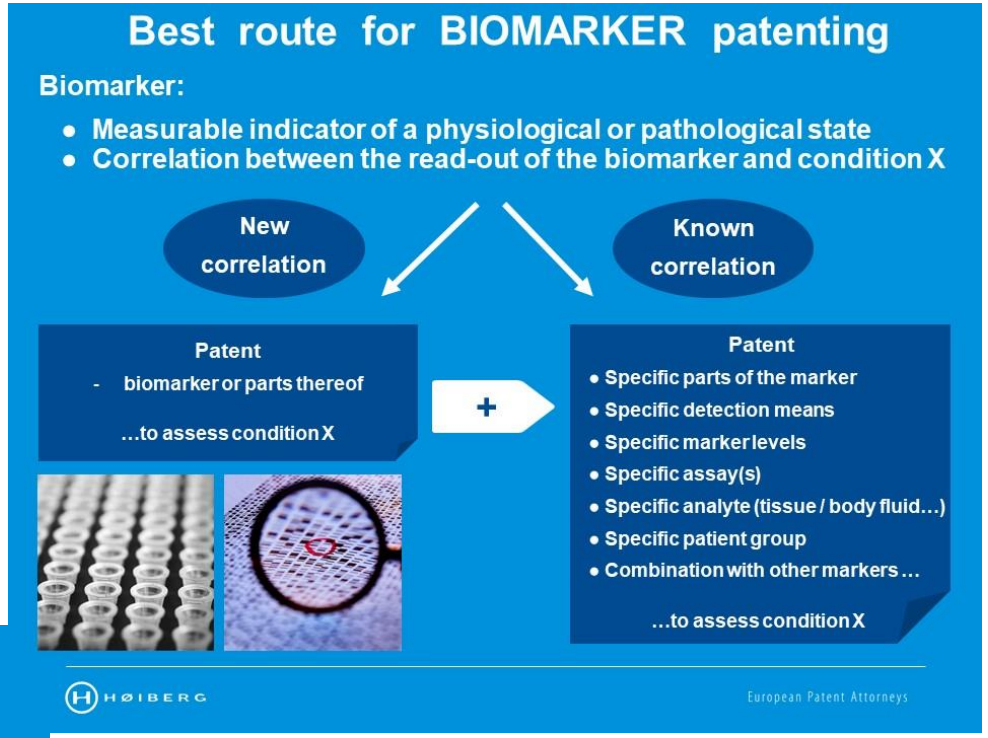
- You will be able to follow the lead to evaluate the potential of the scientific results and help build a case to convince partners or investors and facilitate the communication with them.

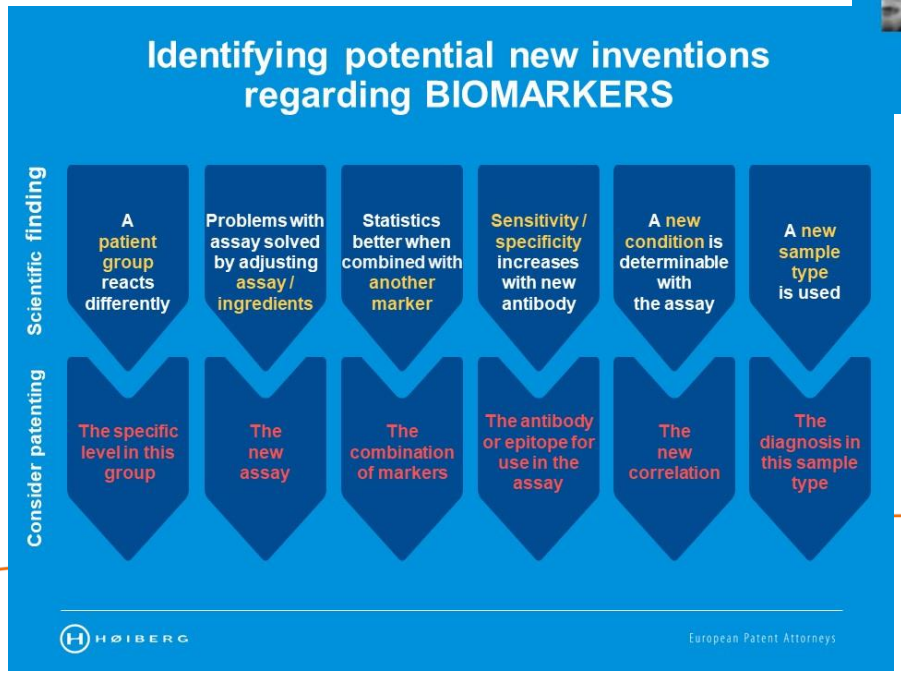
3. Commercialization of Biomarkers

Patenting issues

In the US, Biomarkers are considered products of nature

Diagnosing is a mental act = abstract idea





You will need to

- **Include an unconventional measurement of the biomarker** e.g. new reagents or unconventional sample type (tear fluid, hair follicles etc.)
- **Add a treatment step (companion diagnostic)**
- **If new biomarker,** include a method of detecting / analyzing the biomarker itself
- https://www.uspto.gov/sites/default/files/documents/101_examples_1to36.pdf

Interreg Baltic Sea Region
EUROPEAN UNION
EUROPEAN REGIONAL DEVELOPMENT FUND
BIC

4. The BiC Guide - Demonstration

Demonstration of the BIC Guide

- https://bicguide.biomarker.nu/

BIC Guide

Enter search words...

OVERVIEW

RESEARCH › TRANSFER › MARKET

DISCOVERY | VERIFICATION | PROTOTYPE | PERFORMANCE | MATURATION | IVD ASSAY | LAUNCH

1. Biomarker Discovery

TRL-1 Basic principles observed

TRACKS | DESCRIPTION & ACHIEVEMENTS | DOCUMENTS | EVALUATION

TECHNICAL AND CLINICAL EVALUATION

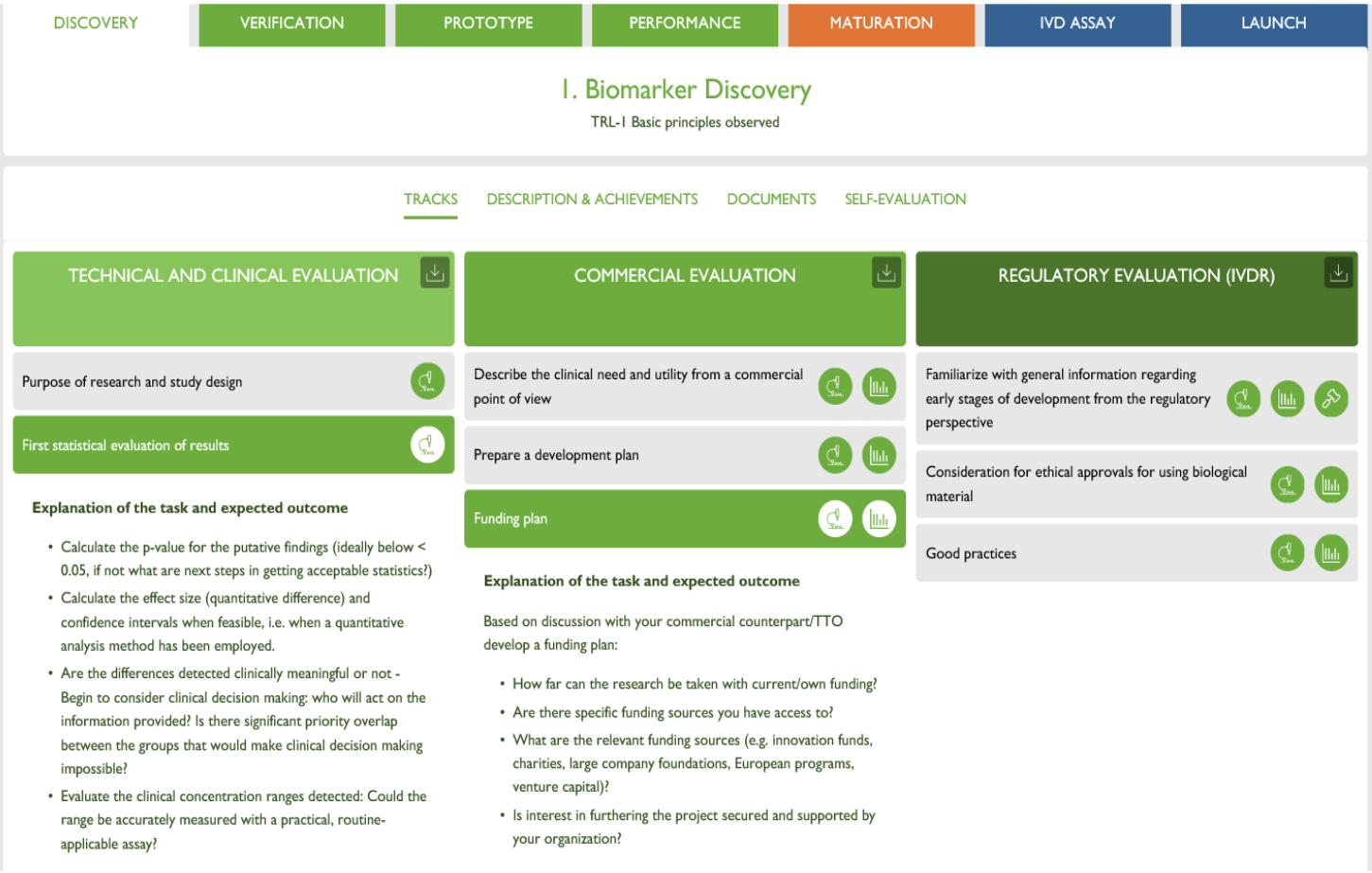
- Purpose of research and study design
- First statistical evaluation of results
- Description of the putative biomarker(s) finding(s)
- Review of literature for the biomarker(s)
- Considerations for panels of biomarkers (biomarker signatures)
- Preliminary stability studies
- Type and purpose of the foreseeable IVD test
- Positioning the test in the clinical care pathway
- Clinical need
- Consistency of results
- Documentation

COMMERCIAL EVALUATION

- Describe the clinical need and utility from a commercial point of view
- Prepare a development plan
- Funding plan
- Collaboration plan
- Summarize your results in a layman way for preparing a declaration of invention

REGULATORY EVALUATION (IVDR)

- Familiarize with general information regarding early stages of development from the regulatory perspective
- Consideration for ethical approvals for using biological material
- Good practices


DISCOVERY
VERIFICATION
PROTOTYPE
PERFORMANCE
MATURATION
IVD ASSAY
LAUNCH
I. Biomarker Discovery
TRL-1 Basic principles observed
TRACKS
DESCRIPTION & ACHIEVEMENTS
DOCUMENTS
SELF-EVALUATION
TECHNICAL AND CLINICAL EVALUATION
Purpose of research and study design
First statistical evaluation of results
Explanation of the task and expected outcome
• Calculate the p-value for the putative findings (ideally below < 0.05, if not what are next steps in getting acceptable statistics?)
• Calculate the effect size (quantitative difference) and confidence intervals when feasible, i.e. when a quantitative analysis method has been employed.
• Are the differences detected clinically meaningful or not - Begin to consider clinical decision making: who will act on the information provided? Is there significant priority overlap between the groups that would make clinical decision making impossible?
• Evaluate the clinical concentration ranges detected: Could the range be accurately measured with a practical, routine-applicable assay?
COMMERCIAL EVALUATION
Describe the clinical need and utility from a commercial point of view
Prepare a development plan
Funding plan
Explanation of the task and expected outcome
Based on discussion with your commercial counterpart/TTO develop a funding plan:
• How far can the research be taken with current/own funding?
• Are there specific funding sources you have access to?
• What are the relevant funding sources (e.g. innovation funds, charities, large company foundations, European programs, venture capital)?
• Is interest in furthering the project secured and supported by your organization?
REGULATORY EVALUATION (IVDR)
Familiarize with general information regarding early stages of development from the regulatory perspective
Consideration for ethical approvals for using biological material
Good practices

DISCOVERY | VERIFICATION | PROTOTYPE | PERFORMANCE | MATURATION | IVD ASSAY | LAUNCH

1. Biomarker Discovery

TRL-1 Basic principles observed

TRACKS | DESCRIPTION & ACHIEVEMENTS | DOCUMENTS | SELF-EVALUATION

PHASE DESCRIPTION

Activities

- Review of scientific knowledge base
- Initial literature and experimental research using qualitative or semi-quantitative methods with selected sample matrices leading to the basic principles of putative new biomarker(s)
- Assessment of basic analytical consistency, statistical significance and scientific validity of results confirmed
- First assessment of novelty
- Hypothesis formulated and techniques selected for scientific validation (proof-of-principle) studies
- Early commercial research on potential use case

PHASE ACHIEVEMENTS

Achievements

- Report of basic principles observed
- Assessment of **statistical significance** performed
- Initial survey of scientific knowledge base and linkages between marker and disease completed
- Tentative development plan drafted
- Tentative commercial approach in-place, including: potential funding sources, partners, options for position in clinical pathway, understanding of alternative technologies/biomarkers/platforms/etc. for competitive awareness and or collaboration
- Raised awareness of potential regulatory requirements, especially pertaining to documentation of results
- Any gaps, in documentation processes identified and steps identified/taken to address these

1. Biomarker Discovery

TRL-1 Basic principles observed

TRACKS | DESCRIPTION & ACHIEVEMENTS | DOCUMENTS | SELF-EVALUATION

- Best Practices on Patient Consentment.pdf
- Best Practices on Clinical Need, Utility and Benefit.pdf
- Best Practices on Clinical Specimens.pdf
- Intellectual Property Rights in Early Stage Projects.pdf
- Tips for a Good Declaration of Invention.pdf
- Tips for Writing a Good Lab Book.pdf

DISCOVERY | VERIFICATION | PROTOTYPE | PERFORMANCE | MATURATION | IVD ASSAY | LAUNCH

1. Biomarker Discovery

TRL-1 Basic principles observed

TRACKS DESCRIPTION & ACHIEVEMENTS DOCUMENTS SELF-EVALUATION

CLINICAL NEED: Is the clinical need suffciently identified and described?

CLINICAL NEED: Have you performed initial statistical significance evaluation of the putative findings and clinical meaningfulness?

CLINICAL NEED: Do you have prepared a plan for testing the consistency of the results and stability?

MARKET: Do you recognize a potential market for your biomarker? Does it fill a gap or otherwise improves current testing scheme?

MARKET: Would your biomarker or biomarker panel improve the current gold standard? (If yes, is the effect of the improved clinically significant?

FEASIBILITY: Can you secure access to clinical specimens for further studies and whether existing ethics approvals cover further work?

FEASIBILITY: Have you made a proper survey on novelty and potential limitations from existing IPR (prior art)?

FEASIBILITY: Do you know, how to finance further steps of commercialization?

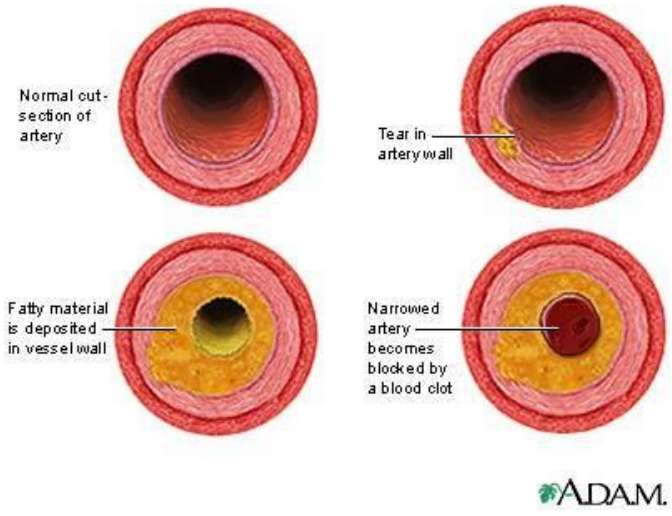
5-10 mn break

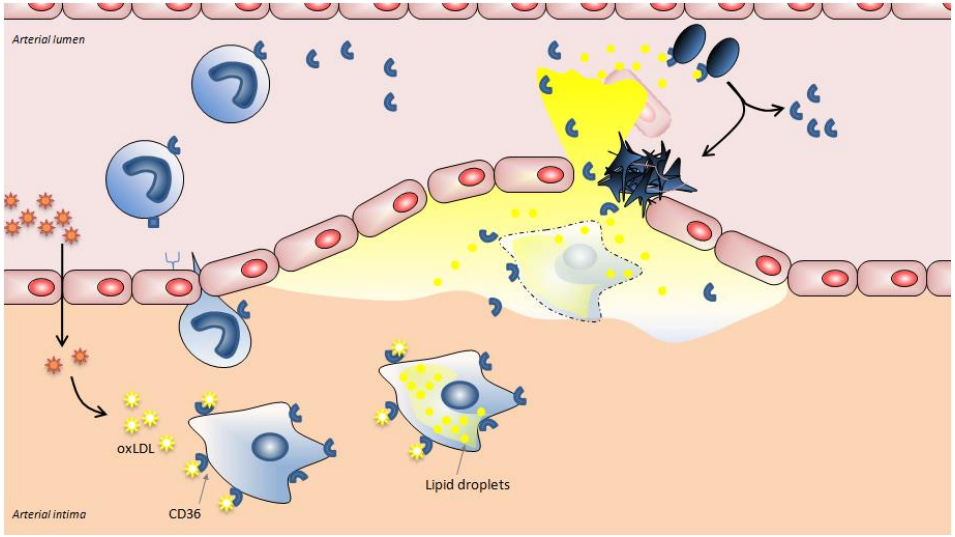
to look at the BIC Guide

https://bicguide.biomarker.nu/

5. A Case story

CD 36 : a story of a support tool based on experience (or lack of…)





We had:

- A method that has been developed, validated and confirmed in several studies.
- A clear clinical need and application (A predictive marker to support decision on treatment and monitor effect of the treatment).
- Good documentation and a large network of partners.
- A market potential due to the high prevalence of obesity world wide.

Could the Review Tool have supported this process?

What we needed and were ready for

- We had a home made ELISA method providing consistent results, which was reproducible in our lab
- We were able to transfer the method for research purpose (or we thought).
- BUT we needed to have a more standardized method to be able to run larger cohorts as our method was time consuming.
- The current method was not compatible with daily routine in a laboratory.
- We needed an industrial partner and evaluated we had material enough.

Expectation to the industrial partner

- We needed competences to process behind the patho-physiology of the disease and understand the biochemistry. Why the specific AB we were working with were able to measure specifically **the signs of** the atherosclerosis process in a patient (Compared to other commercially available kits that where not able to do it). This understanding would help to reproduce the method into industrial production and convert into a method to conduct the test in the lab.

- We needed the development of a standard of the CD 36 protein.

- We needed new AB to ensure the commercial stability of future production

We found the partner, entered a collaboration and did not succeed

Feedback and dicussion on the BIC Guide

- Feedback on the BIC Guide.
- Perspectives and development for the BIC Bridge
  - Finalisation of the development of the 2 last phases related to the industrial development and launch
  - Inclusion of the project management tool
  - Development of training tool for educational purpose
- Achievement for June 2021.

Best Practice Handbook

IVD Guide

Review Tool (Soon available)

Thanks for your participation

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