

approach

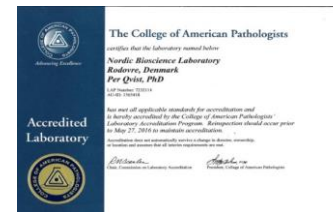


NORDIC BIOSCIENCE

- 80%** of our 180 employees are directly involved in science or research
- 45+** articles are published a year in well respected, peer-reviewed journals with more than **400** publications in total – we are very science-driven
- 80+** abstracts accepted a year at scientific conferences all over the world
- 25** years of experience in biomarker development and integration of biomarkers in clinical trials
- 100** validated proprietary biomarkers in our biomarker portfolio – the fibrosis panel
- 3** FDA/EMA validated biomarkers and **6** biomarkers currently being validated
- >275 000** test results delivered to sponsors from our CAP-certified laboratory in 2018



Biotechnology since 1991



In Vitro Companion Diagnostic Devices
Guidance for Industry and Food and Drug Administration Staff

Document issued on: August 6, 2014

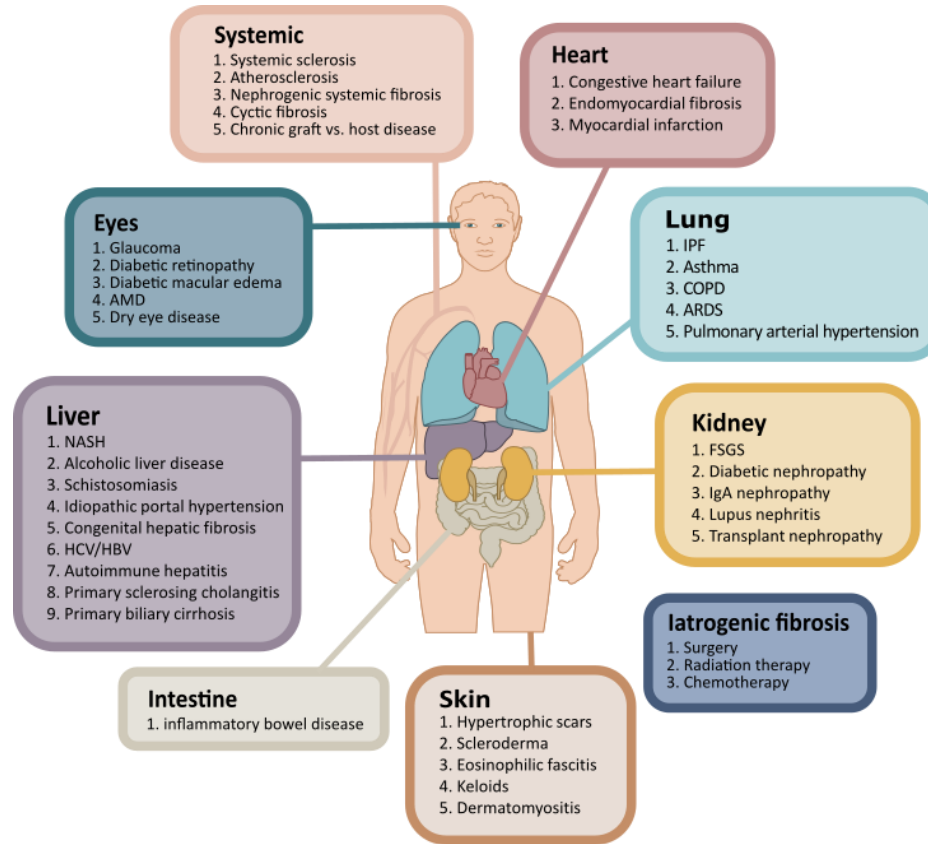
The draft of this document was issued on July 14, 2011.

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U.S. Department of Health and Human Services
 Food and Drug Administration
 Center for Devices and Radiological Health
 Center for Biologics Evaluation and Research
 Center for Drug Evaluation and Research

THE MEDICAL NEED: NON-INVASIVE TECHNOLOGIES FOR PROGNOSIS, DIAGNOSIS & EFFICACY OF INTERVENTION

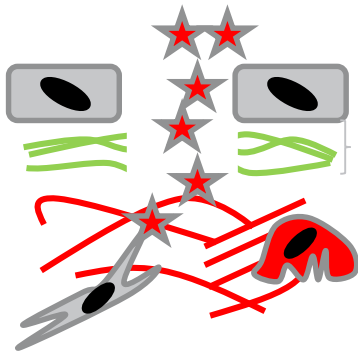


1. 45% of the deaths in western world are associated with fibro-proliferative diseases
2. There more than 50 different fibro-proliferative diseases

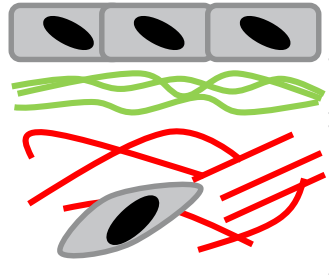
BALANCE OF ECM TURNOVER

SEPARATION OF THE MEASUREMENT OF TISSUE FORMATION AND TISSUE DEGRADATION

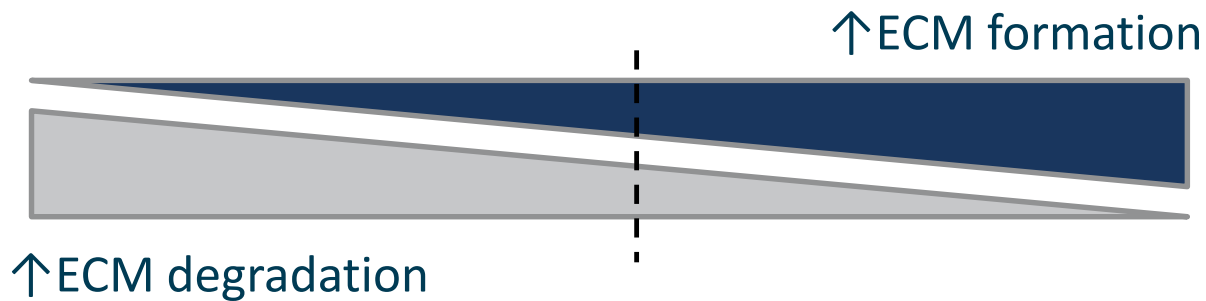
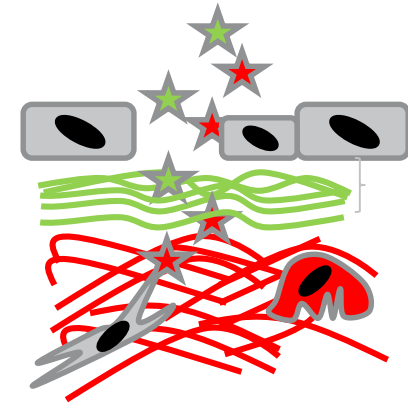
Fibrolysis



Balance



Fibrogenesis



Resolution phenotype

Progression phenotype

PRECISION MEDICINE - QUALIFICATION

OPTION FOR YESTERDAY



10 Potential patients



No patient selection



30% Response



7 non-responders



responders



Non-responders



Serious side effects



Non-treated

OPTION FOR TOMORROW



10 Potential patients



50% selected patients for treatment/non-treatment



60% Response



Non-treated

BEST RESOURCE (SEPT 25, 2017)

Term definition – context of use – the BIG mission

Diagnostic biomarker:

A biomarker used to detect or confirm presence of a disease or condition of interest or to identify individuals with a subtype of the disease

Monitoring biomarker:

A biomarker measured serially for assessing status of a disease or medical condition or for evidence of exposure to (or effect of) a medical product or an environmental agent

Pharmacodynamic/Response biomarker:

A biomarker used to show that a biological response has occurred in an individual who has been exposed to a medical product or an environmental agent

Predictive biomarker:

A biomarker used to identify individuals who are more likely than similar individuals without the biomarker to experience a favorable or unfavorable effect from exposure to a medical product or an environmental agent

Prognostic biomarker:

A biomarker used to identify likelihood of a clinical event, disease recurrence or progression in patients who have the disease or medical condition of interest

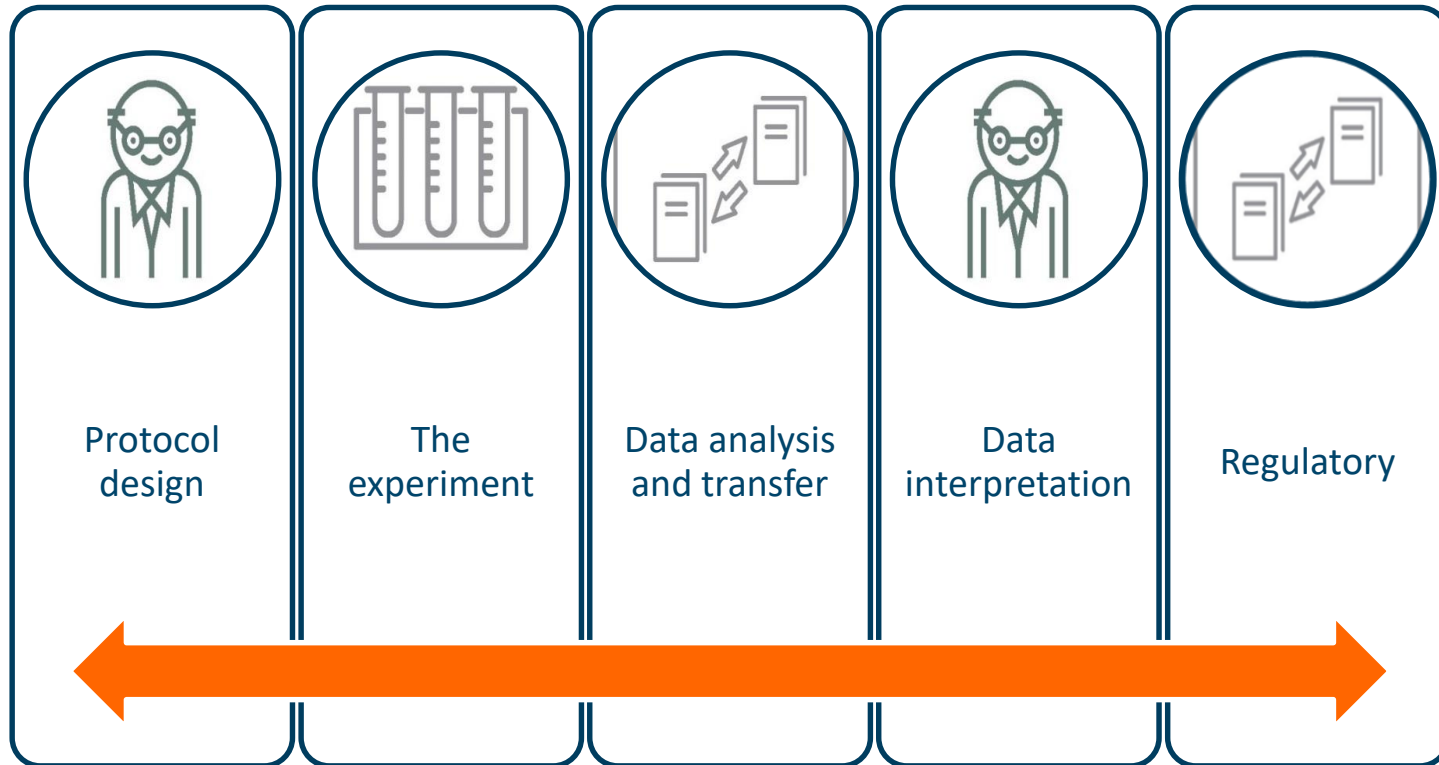
Safety biomarker:

A biomarker measured before or after an exposure to a medical product or an environmental agent to indicate the likelihood, presence, or extent of toxicity as an adverse effect

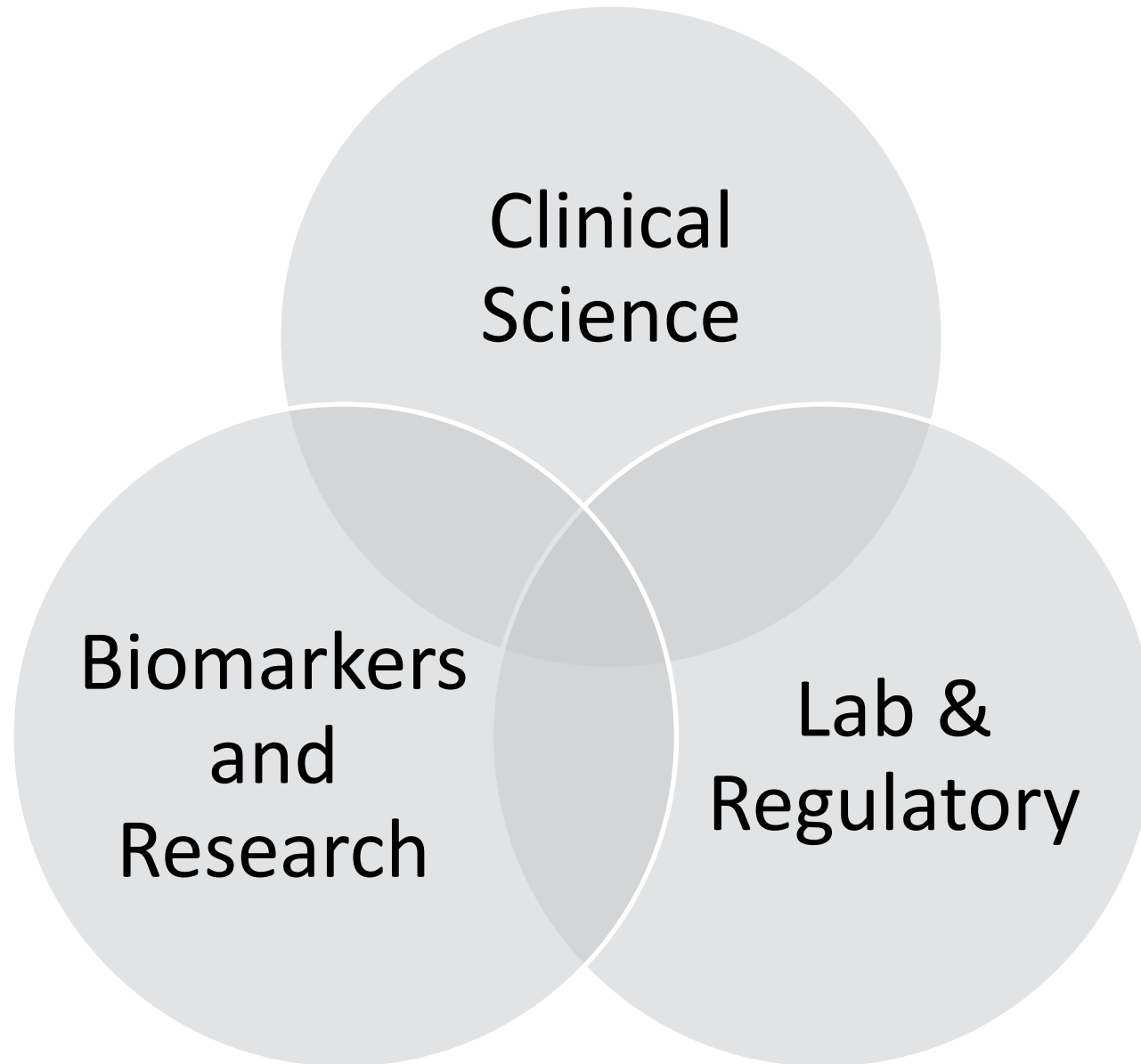
Susceptibility/Risk Biomarker:

A biomarker that indicates the potential for developing a disease or medical condition in an individual who does not currently have clinically apparent disease or the medical condition

THE BIOMARKER POWERHOUSE



WHY IMI



Clinical
Science

Biomarkers
and
Research

Lab &
Regulatory

WHY IMI?

1. A project with an end goal - a product
2. All players support the same vision
3. Controlled science – not deep basic research
4. Industry co-lead with a clear agenda and no fear of confrontation
5. A qualified biomarker to enable patient selection - we can make a difference

HOW TO GET INTO A SUCESSFULL CONSORTIA?

1. Build and know your friends – no last minute calls.
2. Alignment between the project and company vision.
3. Provide a task which is essential for a project – preferably on the critical path to success.
4. Make sure your technology is cutting edge – and no matter what will provide publications and advance the field.
5. Do not be protective – share, share and share.
6. Have a fantastic scientific reputation – and a reputation for publications and not blocking publications.
7. Transparency . . No hidden agenda.
8. Provide the technology to researchers to build data, publications, quality and trust free of charge.

WHY BIG COLLABORATIONS

1. Fun/reputation/credibility
2. Access to smart people
3. Vision of the field - leading the science
4. Regulatory utility meets clinical science
5. Pre-marketing - product pioneers