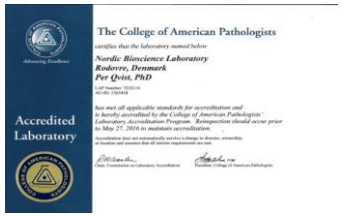
IMI

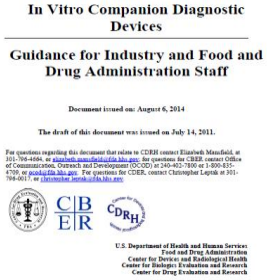
approach

NORDIC BIOSCIENCE

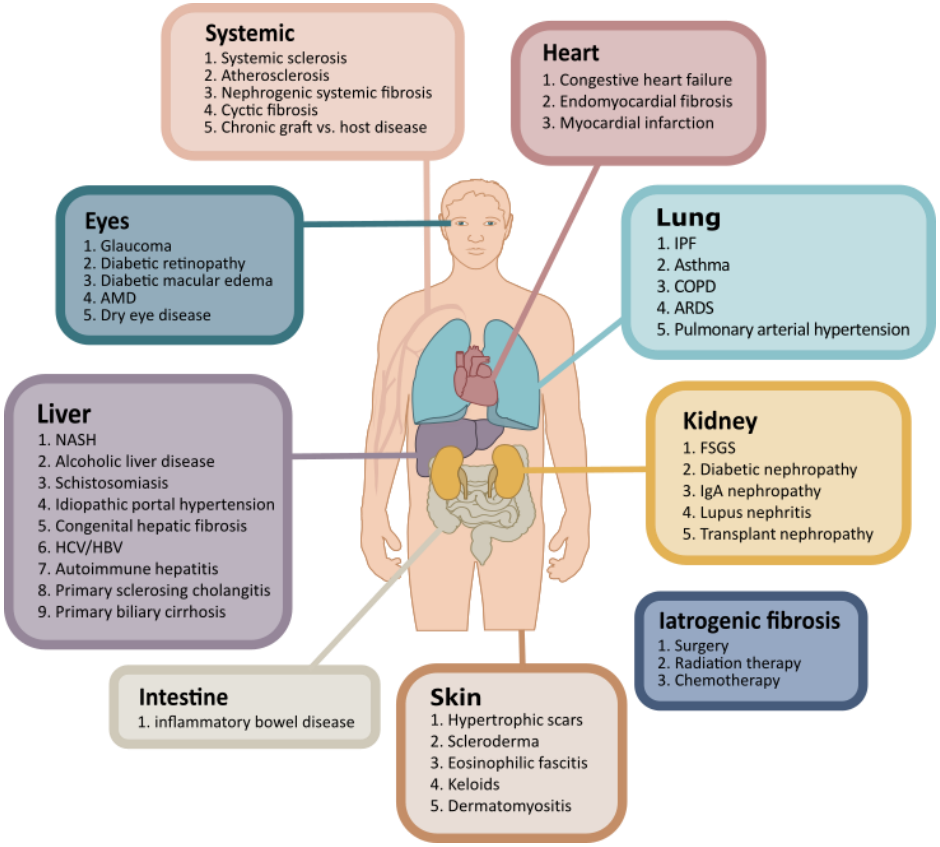
80%	of our 180 employees are directly involved in science or research
45+	articles are published a year in well respected, peer-reviewed journals with more than **400** publications in total – we are very science-driven
80+	abstracts accepted a year at scientific conferences all over the world
25	years 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



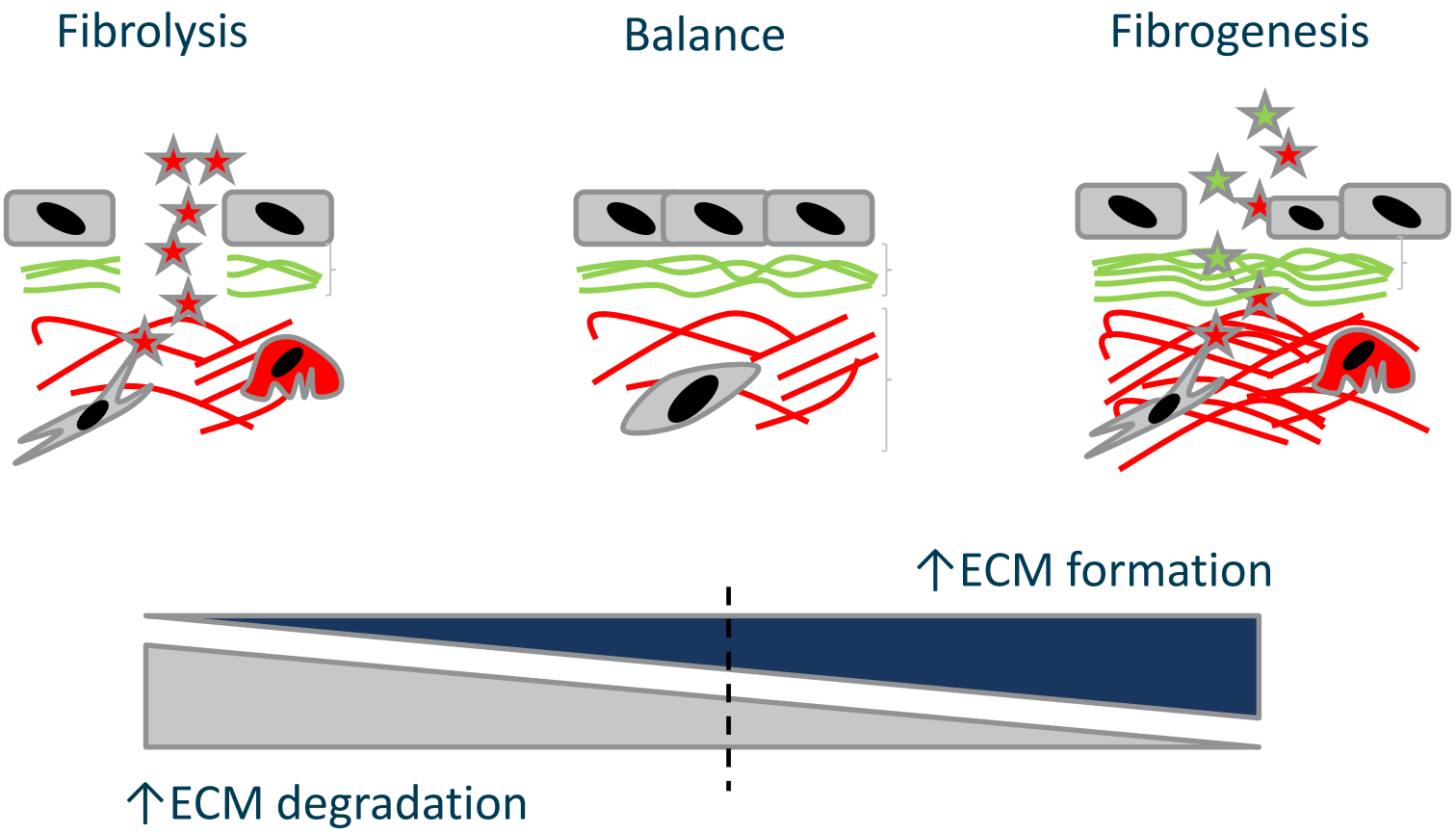


THE MEDICAL NEED: NON-INVASIVE TECHNOLOGIES FOR PROGNOSIS, DIAGNOSIS & EFFICACY OF INTERVENTION

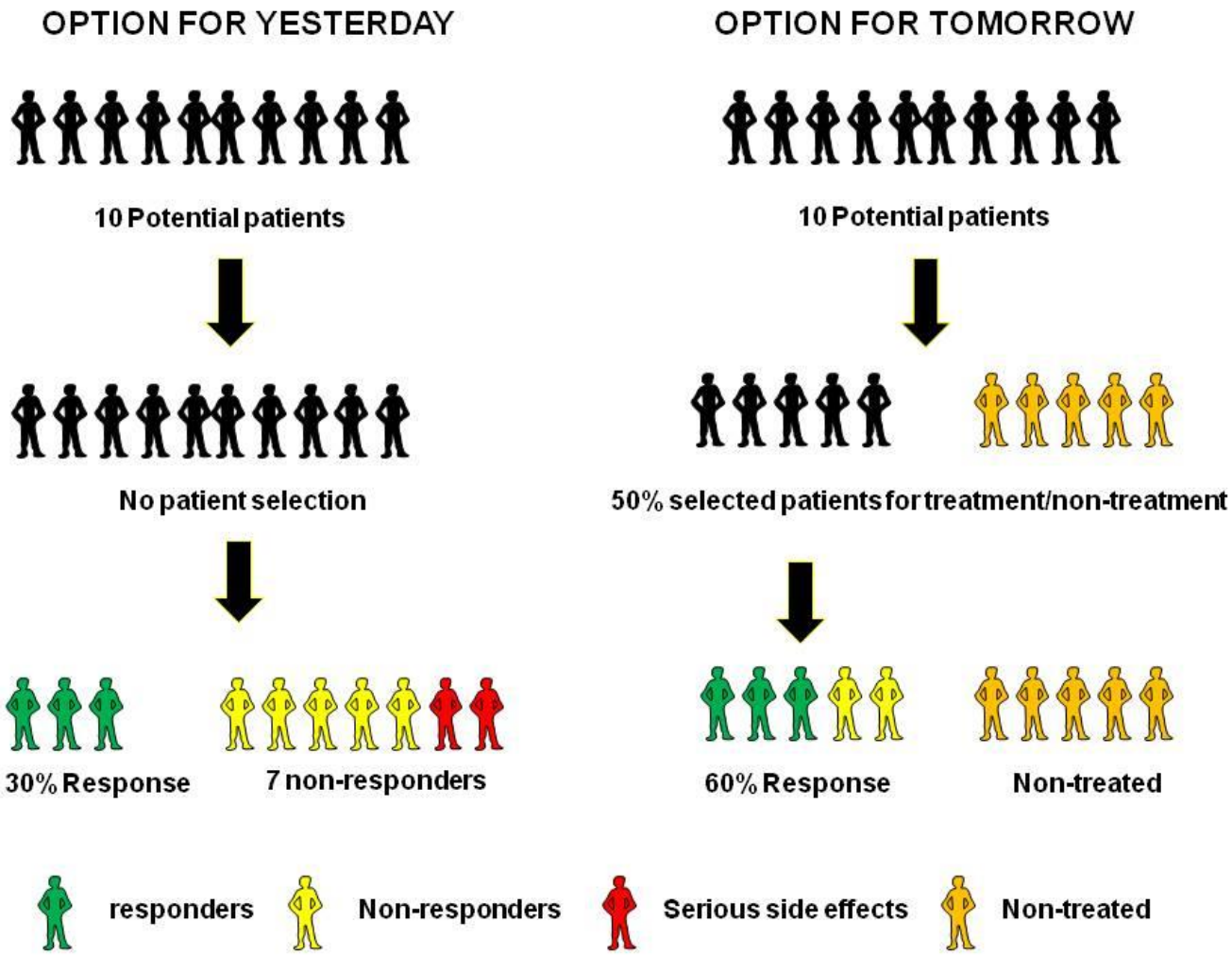


1. 45% of the deaths in western world are associated with fibro-proliferative disease
2. There more than 50 different fibro-proliferative diseases

BALANCE OF ECM TURNOVER
SEPARATION OF THE MEASUREMENT OF TISSUE FORMATION AND TISSUE DEGRADATION



PRECISION MEDICINE - QUALIFICATION



OAC, Karsdal & Kraus, 2014

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:

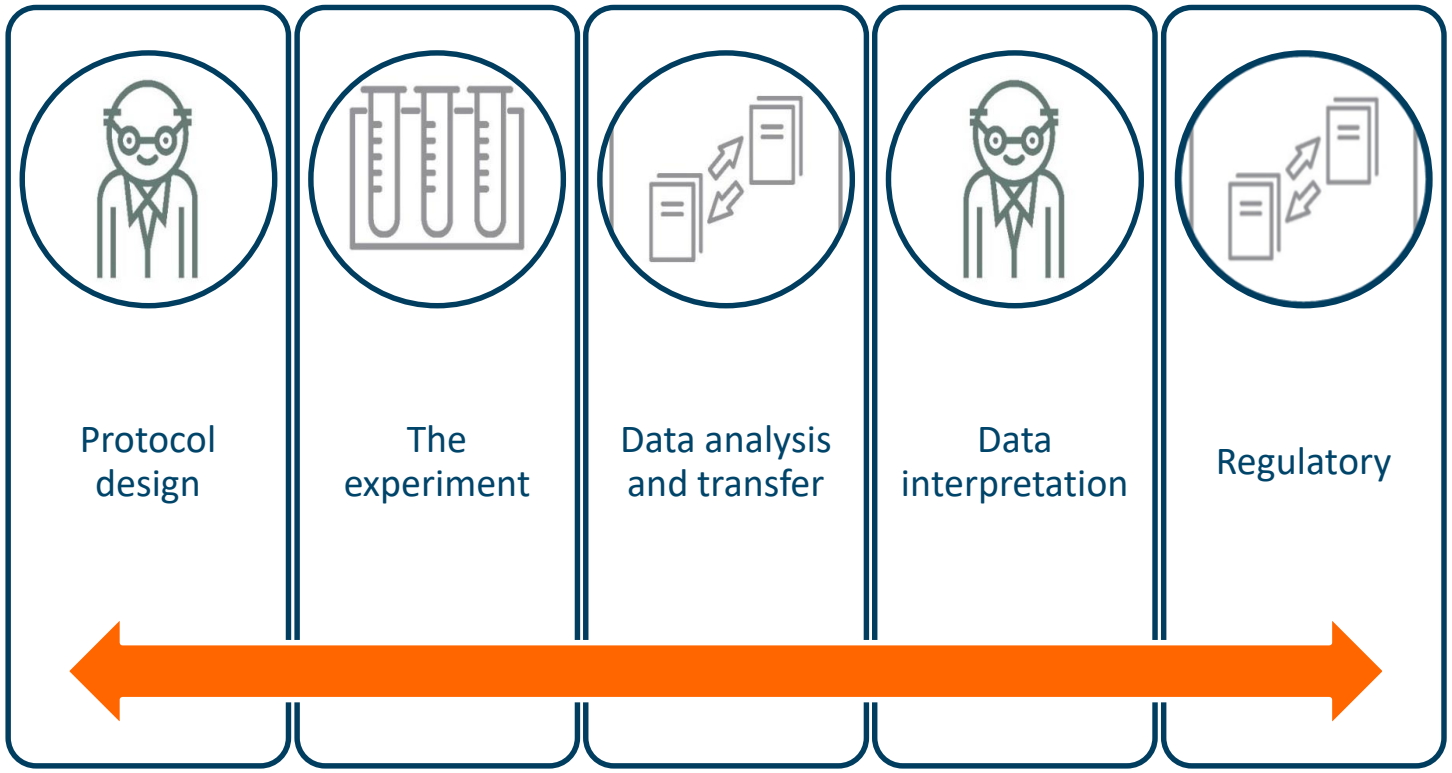
A biomarker measured before or after an exposure to a medical product or an environmental agent to indicate the likelihood, presence, or extent of toxicity as an adverse effect

Susceptibility/Risk Biomarker:

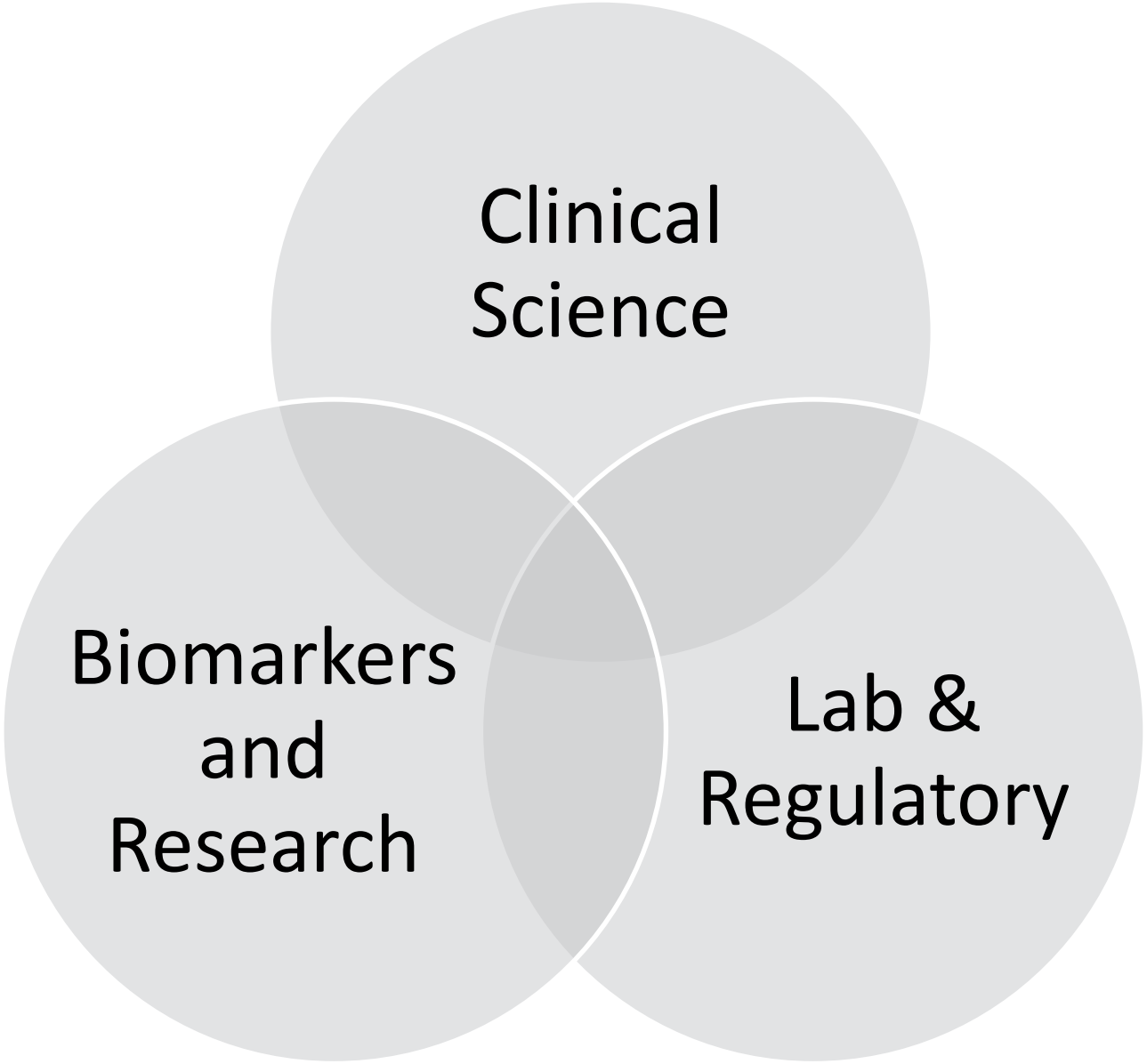
A biomarker that indicates the potential for developing a disease or medical condition in an individual who does not currently have clinically apparent disease or the medical condition

FDA/NIH – Biomarkers, EndpointS and other Tools (https://www.ncbi.nlm.nih.gov/books/NBK326791/?report=reader)

THE BIOMARKER POWERHOUSE



WHY IMI



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 SUCESFULL 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