

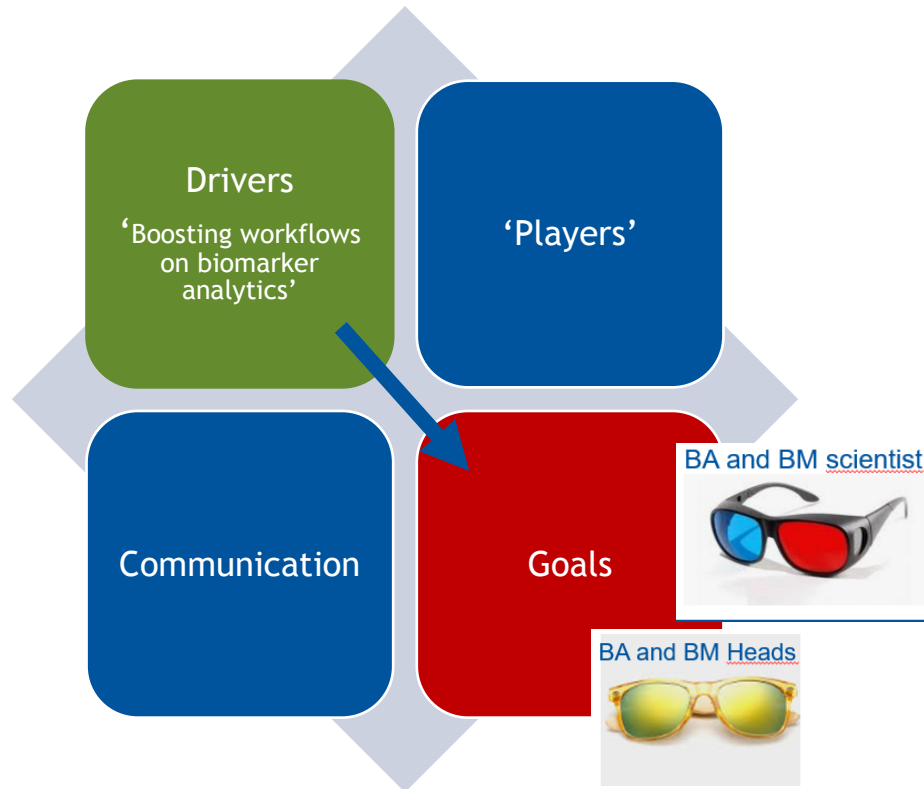


# Boosting workflows on biomarker analytics - early research phase

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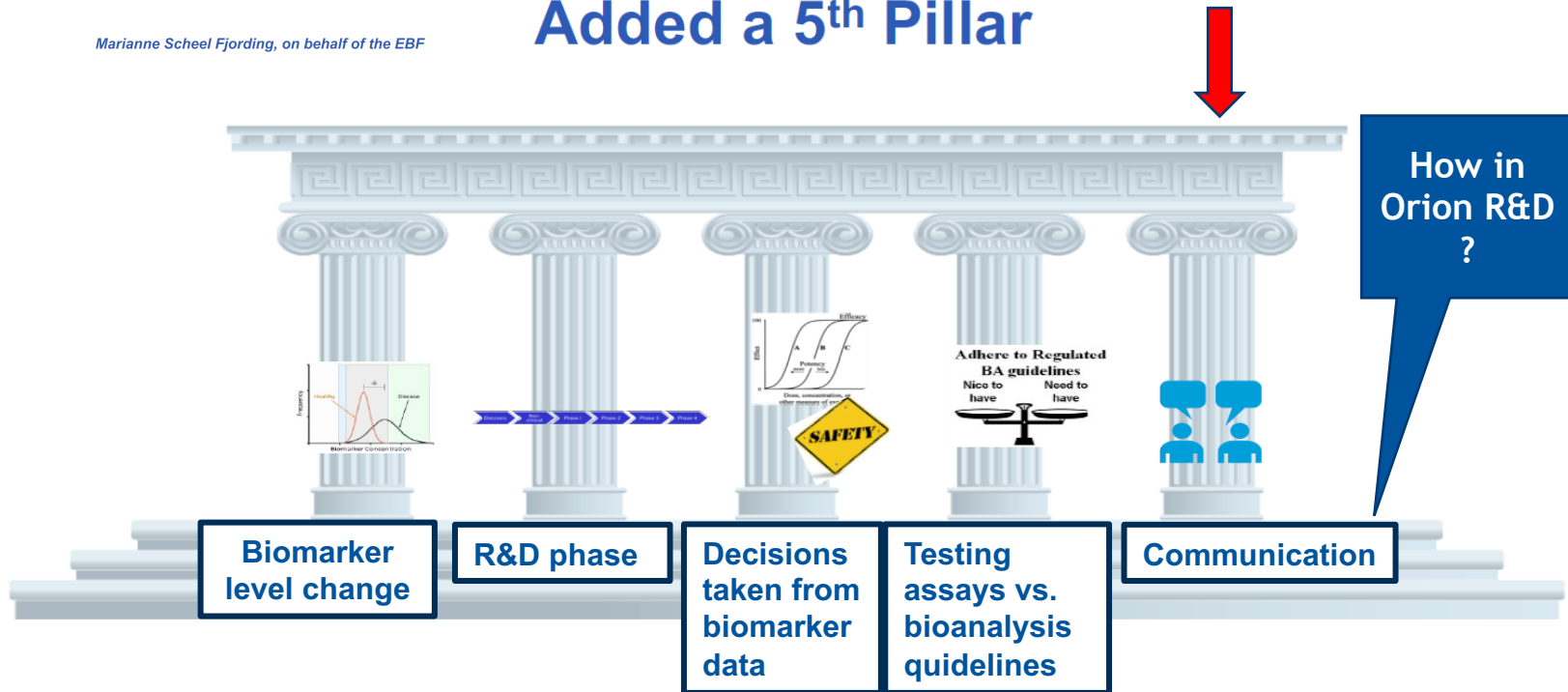
# Content



EBF Biomarker Strategies  
– a new deal?

Marianne Scheel Fjording, on behalf of the EBF

# Communication Added a 5<sup>th</sup> Pillar



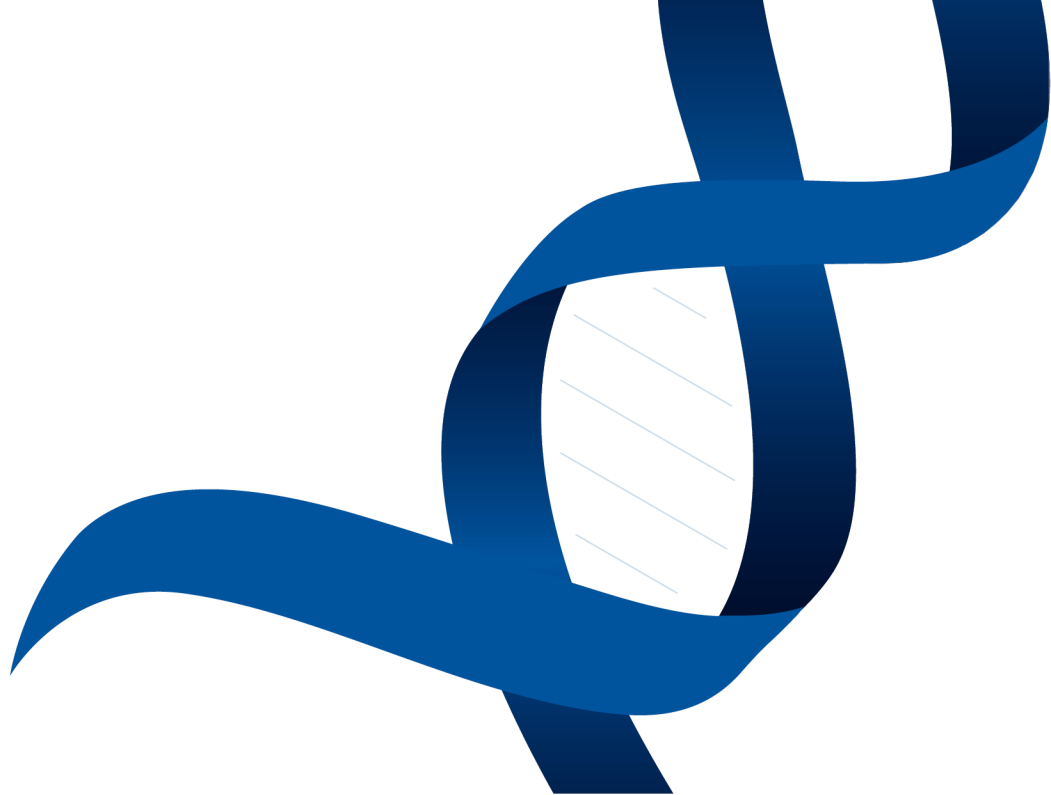
# Orion Pharma R&D

- Our vision is to boost the agility and workflows e.g. in biomarker research



Brain power and  
muscle combined  
with agility of  
a small biotech.

- Our proprietary products therapy areas need world-class biomarker science to succeed
  - Central Nervous Systems
  - Oncology



## Orion Pharma R&D Bioanalytics

# Quantitative bioanalytics group - responsibilities

- Small and large 'Orion-molecules' and their metabolites mainly from *in-vivo* PK/TK studies.
- Developing, testing & validating LC-MS/MS and LBA bioanalytical methods.

Last 5-10 years ever growing need for endogenous biomarker analytics (LC-MS/MS)



Brain power and muscle combined with agility of a small biotech.

# Our goal is smooth project work and optimized resourcing of 'PK and biomarker' bioanalytics

## In Orion laboratory

Non-regulative bioanalytics of Orion 'hits, leads and candidates'

Non-regulative Biomarker analytics in early research (endogenous pharmacodynamic and safety biomarkers)

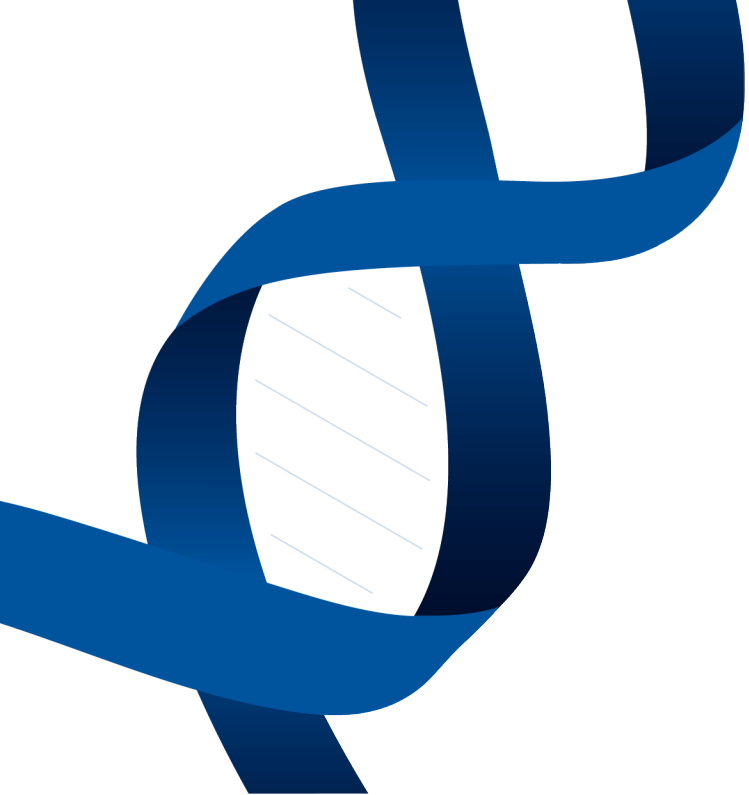
## In CRO laboratories

Regulative Bioanalytics in animal and human studies

Biomarker analytics in clinical studies

Regulative bioanalytics in BE studies

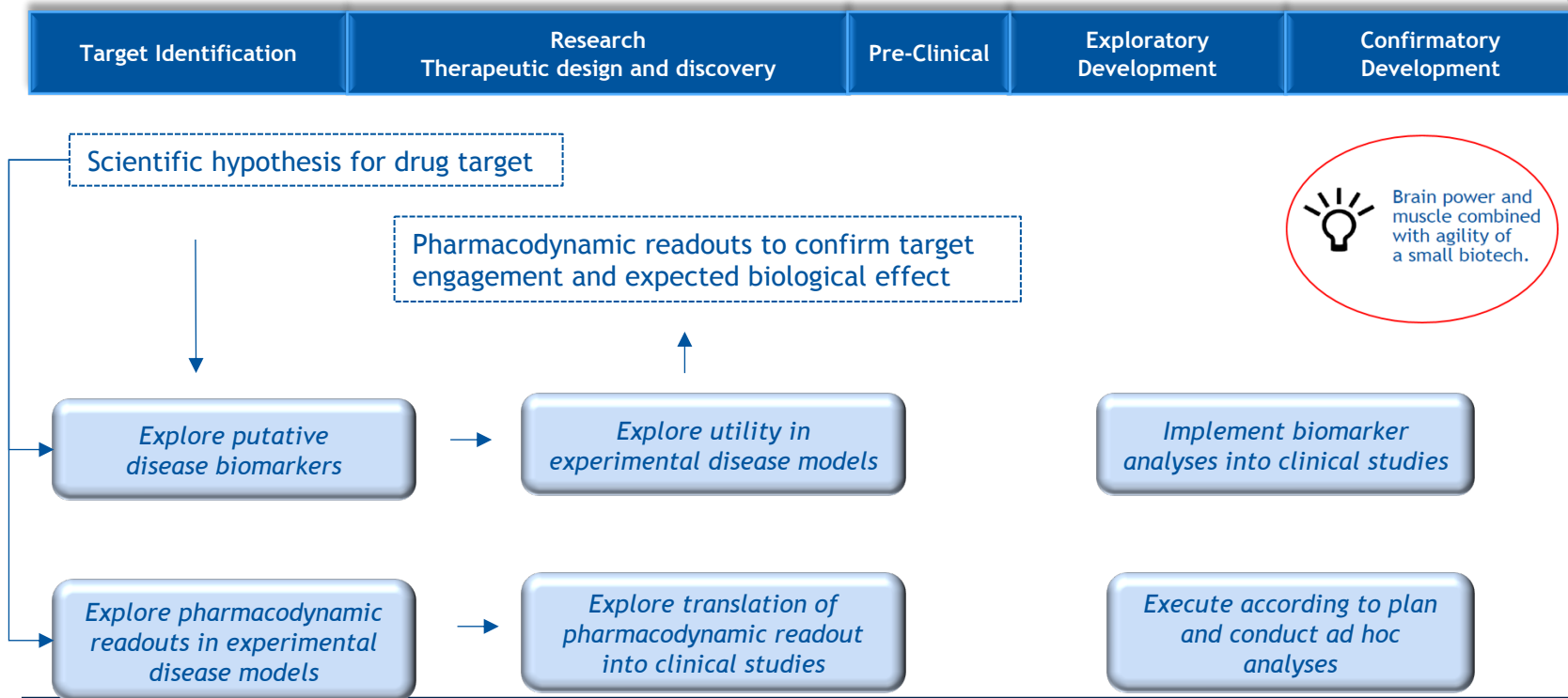




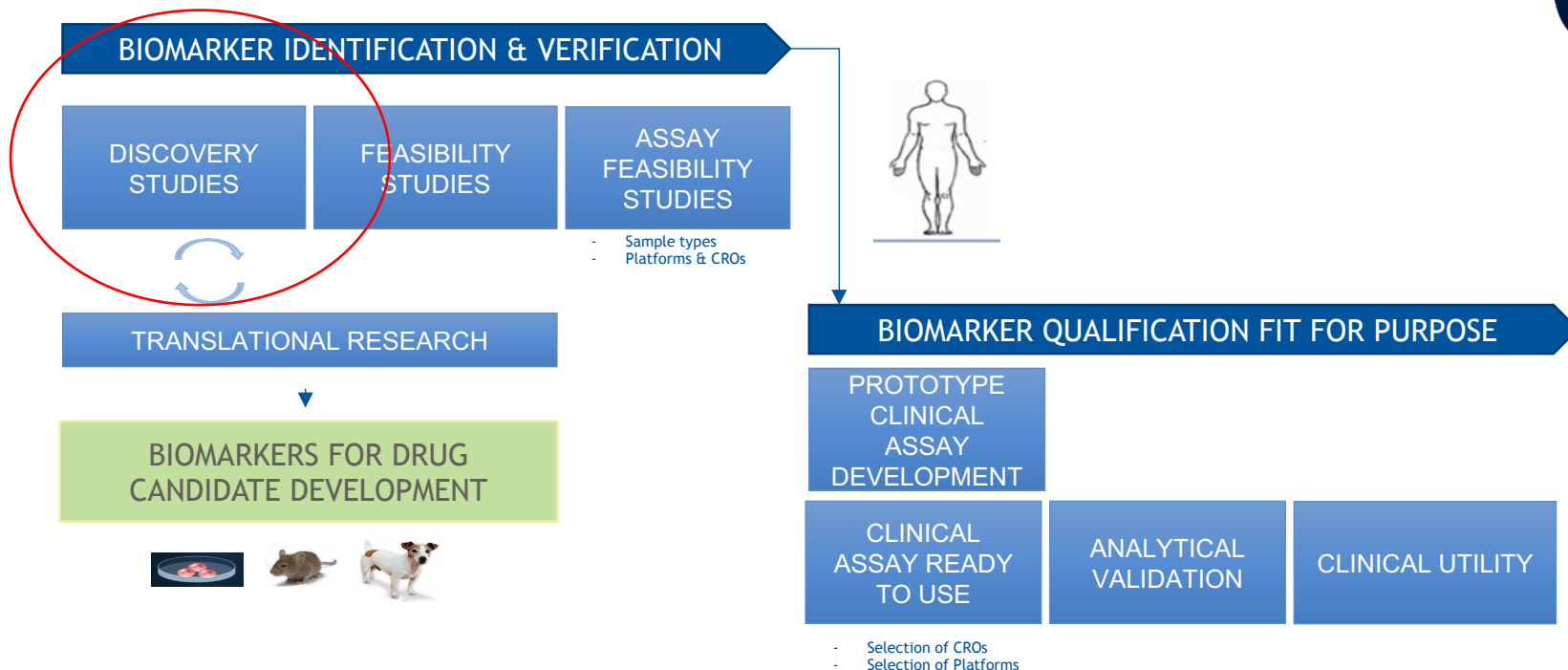
## Orion Pharma R&D Biomarkers

# Biomarker Scientist will be engaged to project at drug target assessment phase

- As a member of multidisciplinary team provide scientific leadership in translating preclinical hypothesis into a clinical biomarker strategies



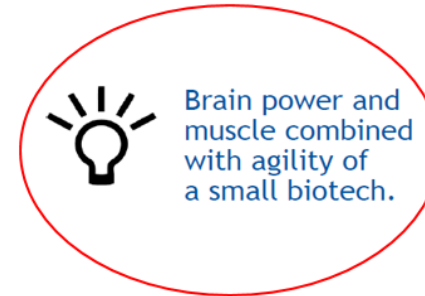
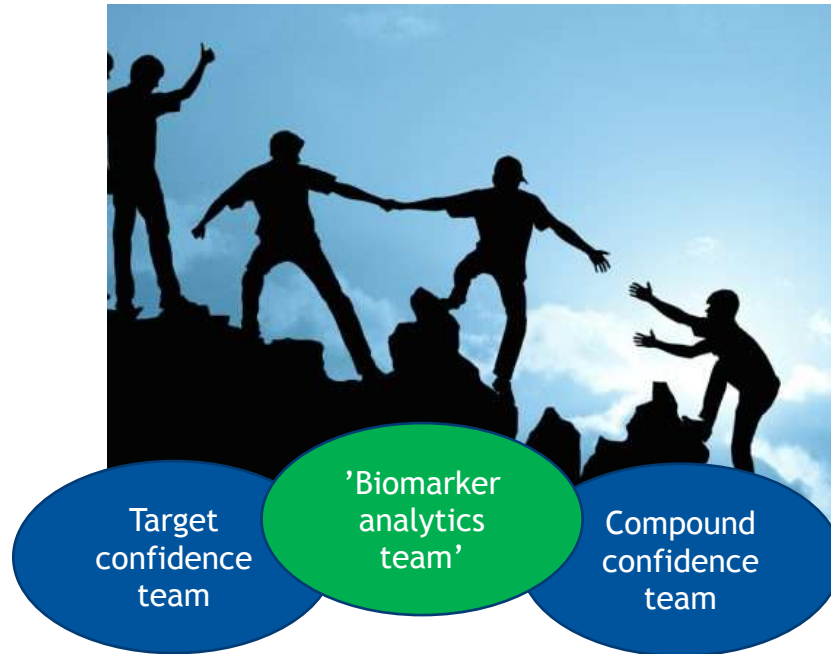
# Biomarker development workflow

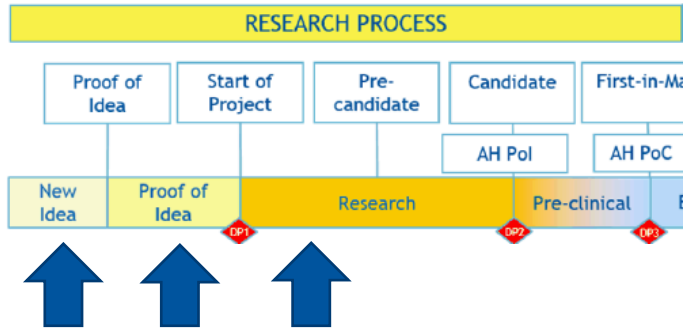


# Teams in R&D projects

'Players' in new 'Biomarker analytics team'

- Biomarker scientist, bioanalytics scientist and *in vivo/in vitro* pharmacology scientist





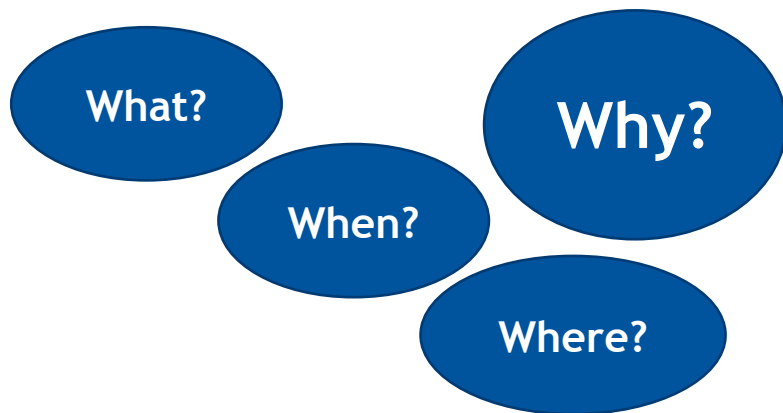
Biomarker analytics  
planning & discussions  
needed.

1) When?

2) Who?

# Roles and responsibilities in 'biomarker analytics team':

**Biomarker scientist and/or  
PK/PD scientist**



**BA scientists**



LC-MS/MS and  
LBA methods



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# Workflows in early research phase

## Scientists (in projects)

- 1) **Meet and plan** the studies on biomarker issues in bioanalytical point of view
- 2) **Clarify** objectives of the bioanalyses
- 3) **Discuss and understand** the requirements for bioanalytical methods vs. contexts of use of biomarker data

## Heads (operational)

- 1) **Support** projects workflows
- 2) **Anticipate**
- 3) **Prioritize**
- 4) **Optimize** resourcing

# Improved workflow on biomarkers analytics in early research phase

BA and BM scientist



Past

- BM scientist not always involved in project team discussions.
- In-vivo pharmacologist often ideating the biomarkers to measure.
- Discussion on biomarker bioanalytics insufficient.
- Testing needs for biomarker methods unclear, eg. sensitivity, stability, specificity.

Now

- Biomarker analytics team in pilot projects started.
- BM, BA and Pharmacologist plan the BM studies together (sampling, method development and testing).
- Suitability of the assay method to answer the research question in focus.

Future

- BM, BA and Pharmacologist involved in all early phase projects BM-discussions → more relevant planning of studies and optimization of BA methods.
- Testing and validation of methods relevant - not 'tick-box' routine.
- Finding more synergies between projects.

Our Goal!

Amount of biomarker ideas and their analytics needs in early phase projects is growing.

# Improved workflow on biomarkers analytics in early research phase

BA and BM Heads



Past

Now

Future

- Context of use of BM data often missing.
- Difficult to prioritize, prepare and resource.

- Bioanalytics discussion started in two early phase pilot projects
- Workflows clarified via pilot projects
- Follow-up & tuning of operational teams

- Clear plans and execution.
- Efficient resourcing.
- Smooth project progression.

Our Goal!

Amount of biomarker ideas and their analytics needs in early phase projects is still growing.



***Acknowledgements:***

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***Meri Ramela, Senior Scientist, Bioanalytics***

***Thank you!***