

BioX Operations Specialist and Bioanalytical Manager

Combined role for a new approach of the biosample strategy

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Some operational questions that arise during a clinical study ?

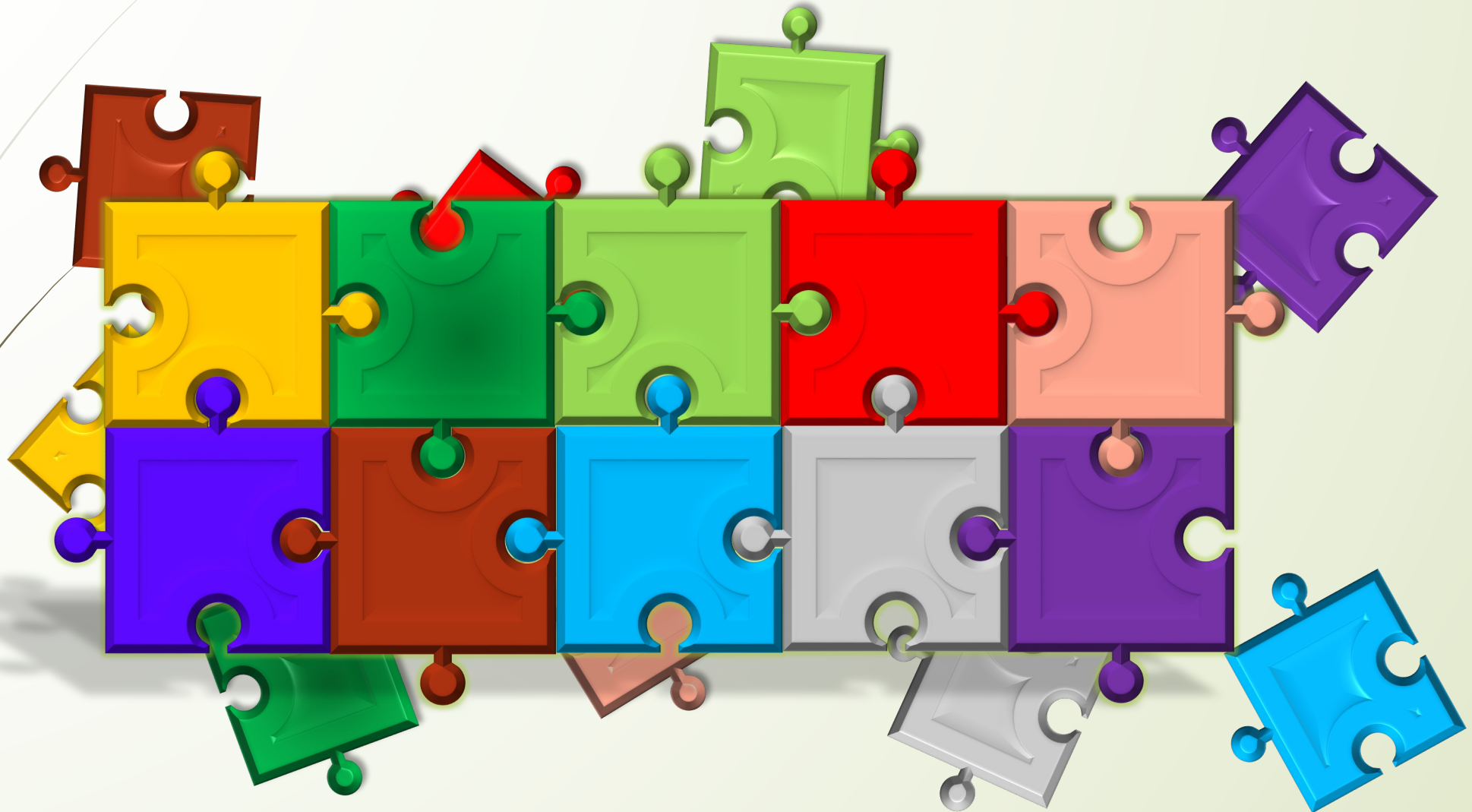


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-  How can the Biomarker strategy be successfully implemented ?
-  Budget planning/forecast ?
-  Expected turnaround time from sample collection to data delivery in house ?
-  Can samples be analysed within a fast turnaround time?
-  LLOQ sensitivity ?
-  Tissue slide aging?
-  What laboratory should be used for the prospective tissue testing ?
-  Assay development strategy ?
-  Where are my samples ?
.....

How can a study team get the answers to all these questions and more ?

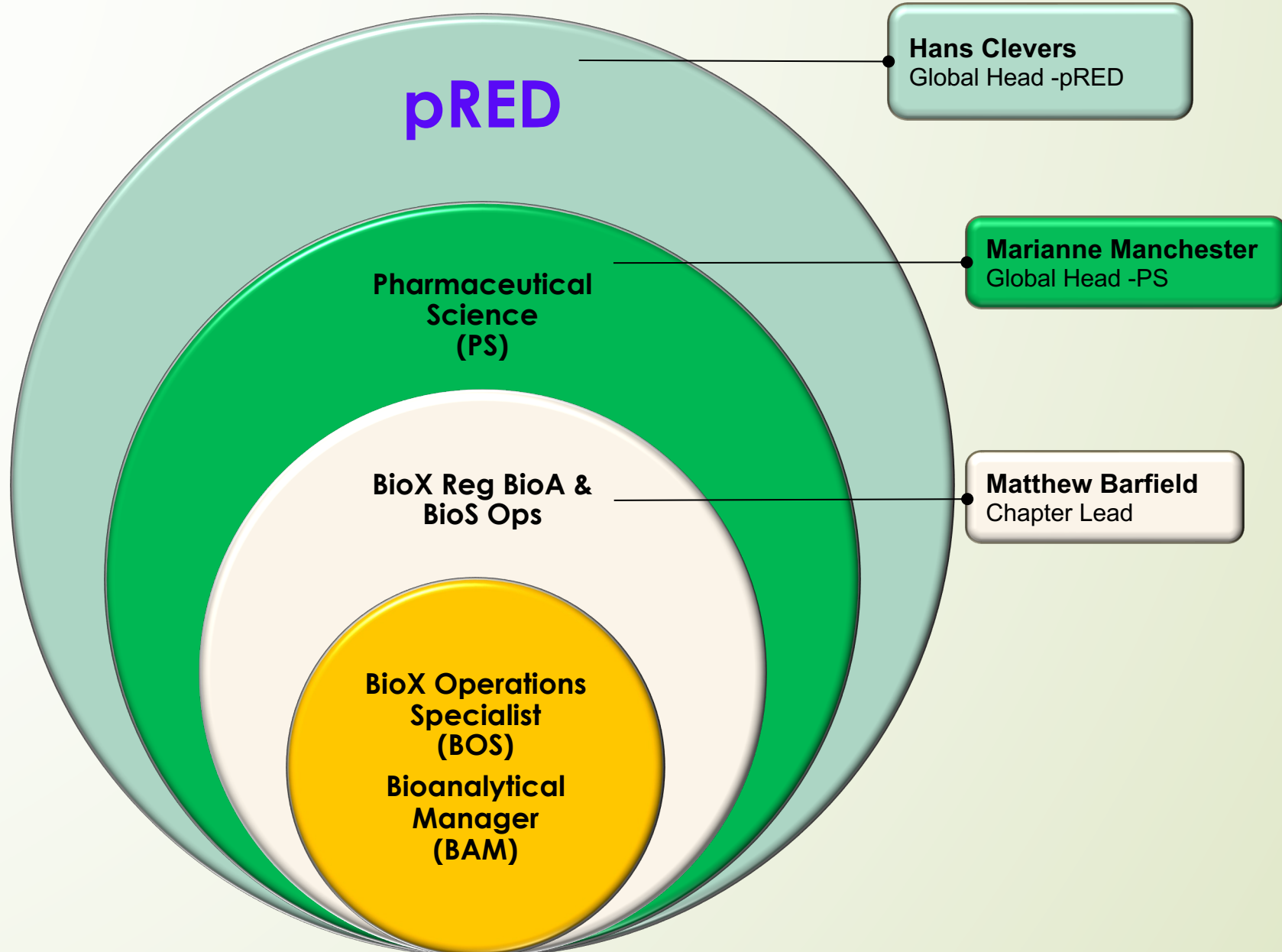
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Structure

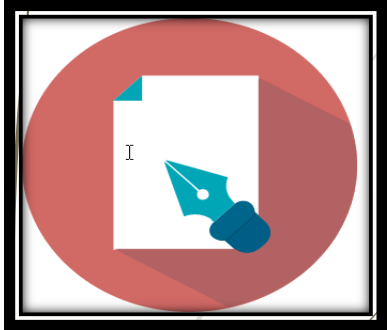


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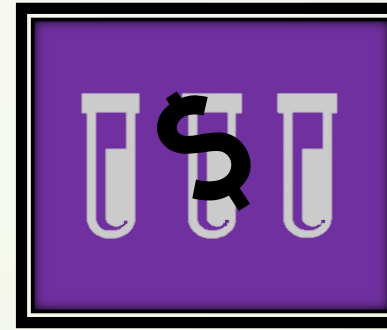


Some of the Key functions of BioX Operations Specialist

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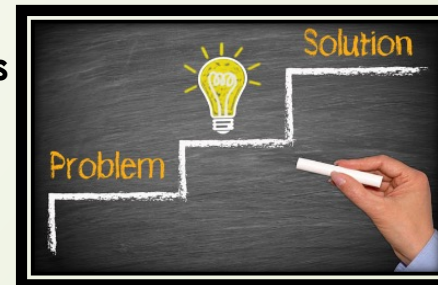
- **From synopsis writing** to Protocol / ICF finalization
- **Bio-sample strategy/ expertise**
- **Guide , input and** support the Biomarker team/ study team



- Responsible for all **budget management**
- **Accountable and Responsible** for the vendors oversight
- Sample management



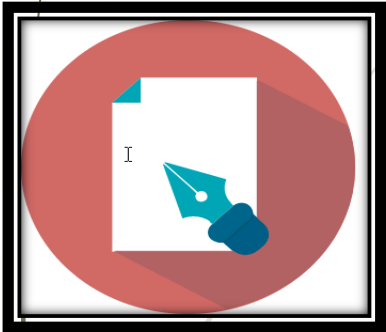
- **Core** team member of the BioX expert team
- Close collaboration with **all internal stakeholders**
- **Impact** on the Biomarker strategy
- **Involved** on the laboratory selection process
- Provides operational Expertise



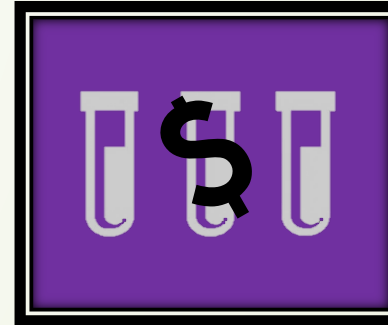
- **Primary point** of escalation

Some of the Key functions of Bio Analytical Manager

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- **Trained bioanalytical scientist** assigned at pre-clinical stage
- Review **protocols**
- Review and contribute to documents for regulatory submissions



- Contract **set up**
- **Work closely** with Meth/Dev team to transfer the assay
- **Manage** and direct the analysis of samples



- **Support and co-develop** PK/PD/ADA analytical strategies
- **liaise and interact** with stakeholders across the organization
- **Manage** all regulated bioanalytical aspect
- **Support** filling and interact with HAs



- **Primary point** of escalation
- **Ensure PK/PD /ADA Sample** analyses & Data transfer on time

Added values of a combined role ?

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- Process **simplification**
- Assigned at **pre-clinical**
- Brings molecule **knowledge** to EIH
- Involved from **early** synopsis writing to protocol **finalization**
- **Better** integration into the study team/Clinical team/Project Team
- Easier communication between **all parties** involved
- **Efficiency** gain from meetings

Added values of a combined role ?



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- **One single** point of contact for all Q related to Bio sample strategy
- **TAT** and **Data delivery** discussion aligned earlier
- **Contracting** and **budget** projections better under control
- **Complete** control of all vendors (contract & management)

Added values of a combined role ?

- **Assay development** : bridges gap between Biomarker team and BioX/PS
 - **Helps** develop Context of Use (COU)
- **Better clarity** :
 - In some project PD markers (soluble) are under BAM remit and in other Project under BOS/Biomarker expert
- **No surprises** of regulated biomarkers because BOS/BAM responsible for all biomarkers

Where are we ?

- **Two** BOS/BAM currently assigned on different projects
- **Pilots** started in Feb 2022
- Covering **2 Diseases** area
 - ✓ 2 projects in **Oncology**
 - ✓ 1 project in **Immunology**
- Gathering **feedback** from stakeholders all the way through
- More to come ...

First Impressions ?

- **Personal development**

- Great opportunity to learn new skills
- Greater involvement and importance to project team
- Involvement in a broad range of scientific and strategic topics
 - Opportunity to have a better oversight of studies
- Broad range of scientific activities and workflows
 - PK/ADA/NAb/Biomarkers/Flow Cytometry/Tissue analysis/Genetic assays/safety...

- **History** of the molecule before EIH

- Challenges encountered in Tox. studies
- Great opportunity to gain efficiency and better advise the team (full oversight)

Acknowledgement

pRED BioX Reg BioA & BioS Ops

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- ✓ Jasbinder Bajaw
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- ✓ Matthew Barfield

Thank you !



Doing now what patients need next