Sobi's organization around Biomarkers

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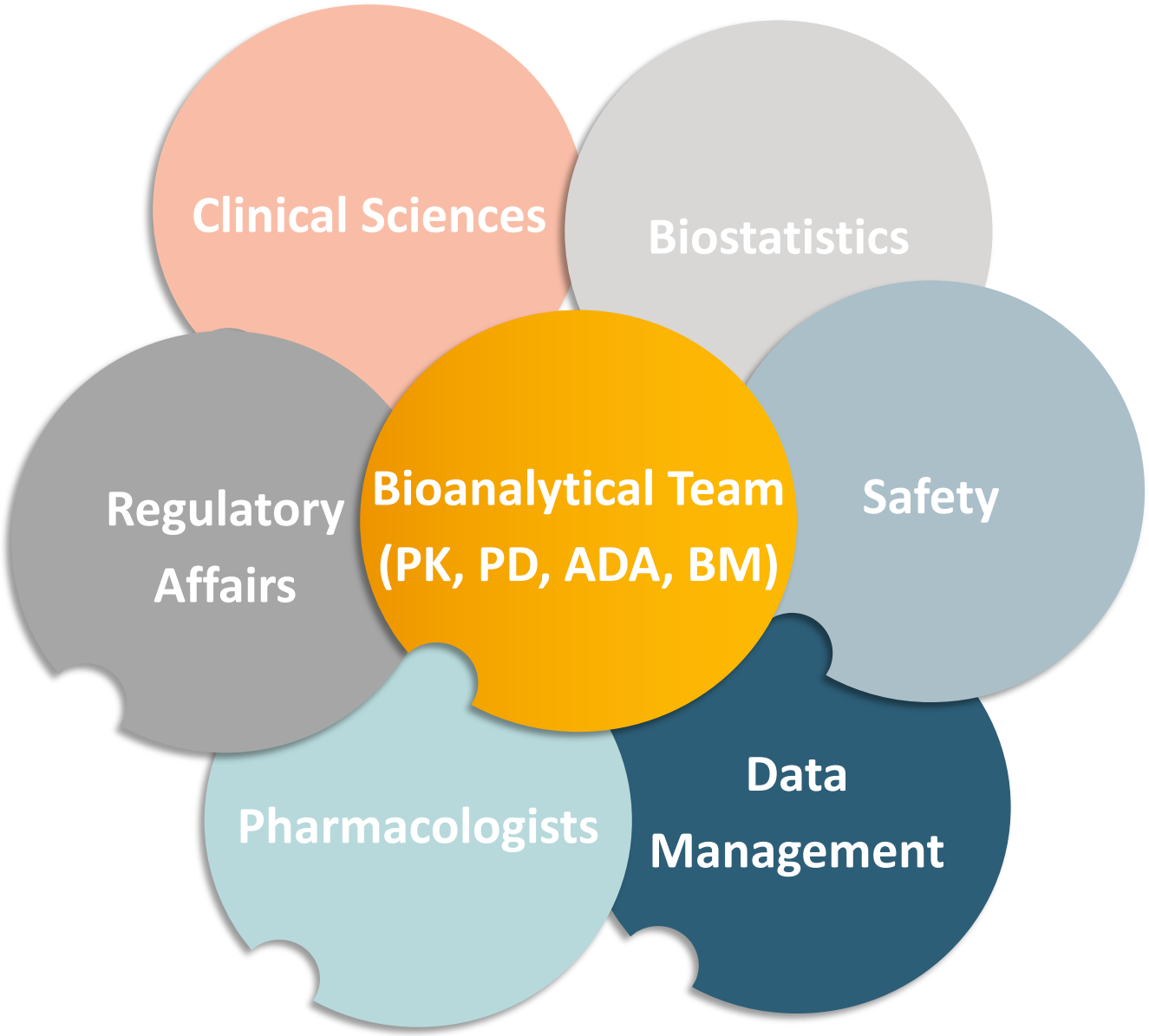
Swedish Orphan Biovitrum (Sobi)

- Head office in Stockholm, Sweden, spans more than 30 countries
- Focus on two therapeutic areas – Haematology and Immunology
- Aim at strengthening its late-stage pipeline
- Key products encompass small and large molecules
- Bioanalytical work stretchs from clinical Phase I to Phase IV
- Biomarker validation can be internal or performed by a CRO

Still the challenge is the same: understand what's needed by clinical stakeholders

International biopharmaceutical company focused on rare diseases

Bioanalytical work within Sobi's organization



- No «officially dedicated» team for translational aspects or Biomarkers in current organization
- Input from Bioanalytical Team requested for the methodology only
- Clinical protocol developped by clinical team only, without involving (or too late) the Bioanalytical team
- Bioanalytical team at the interface with many stakeholders

Driver for GCP & GCLP requirements for Biomarkers

Clinical Study Objectives /Endpoints	GCP	GCLP & Fully validated methods (guidelines)	CoU
Primary (main)	Yes	Yes	Only if data are used for Regulatory Decision or for Decision making such as for patient dosing
Secondary (following)	Yes	Yes/No	
Exploratory	Yes	No	Other from above

- **Use of «exploratory» term: BA validation versus clinical use!**
- **Use of a designated Biomarker can evolve through study phase and/or indication: the CoU depends on clinical study**

Challenges around Biomarkers as per current situation

1. Around the CoU

In general there is no CoU defined in the clinical protocol

Drift in the CoU from exploratory to decision making within the same clinical protocol (no protocol amendment) e.g. if exploratory data appear to be highly valuable

Need of fast turnaround data must be justified by a CoU (not always the case)

The overall clinical protocol timelines sometimes preclude from better exploring the biomarker CoU

2. Role of the BA team

Role of bioanalytical team is essential in early discussion i.e. during clinical protocol development

Not always clear that BA team is not involved in safety parameter or hemato-biochemistry measurement e.g. glucose or ferritin

Challenges around Biomarkers as per current situation

3. Around clinical team strategy

Usually absence of well-defined Biomarker strategy for same drug used in different indications

Biomarkers are sometimes triggered by KOL (e.g. PI) with no background in bioanalytical sciences

Measuring exploratory BM might raise more questions/ more issues (does it preclude from using more exploratory BM to better understand MoA?)

Difference between a biomarker bioanalytical validation and a biomarker clinical validation, and the regulatory constraints around

Wording within the clinical protocol is too vague (on purpose?)

Levels of other potential disease markers (e.g. BM1, BM2…)

Additional PD biomarkers may also be evaluated

Serum concentrations of other relevant markers, including but not limited to BM1, BM2

Having the appropriate insight into the Biomarker final evaluation is key in refining the CoU and adapting the appropriate level required of (cross)validation, or bridging activities for the assays