Huntingdon Life Sciences
Working for a better future

A Tiered Approach to Bioanalysis: From Concept to Practice

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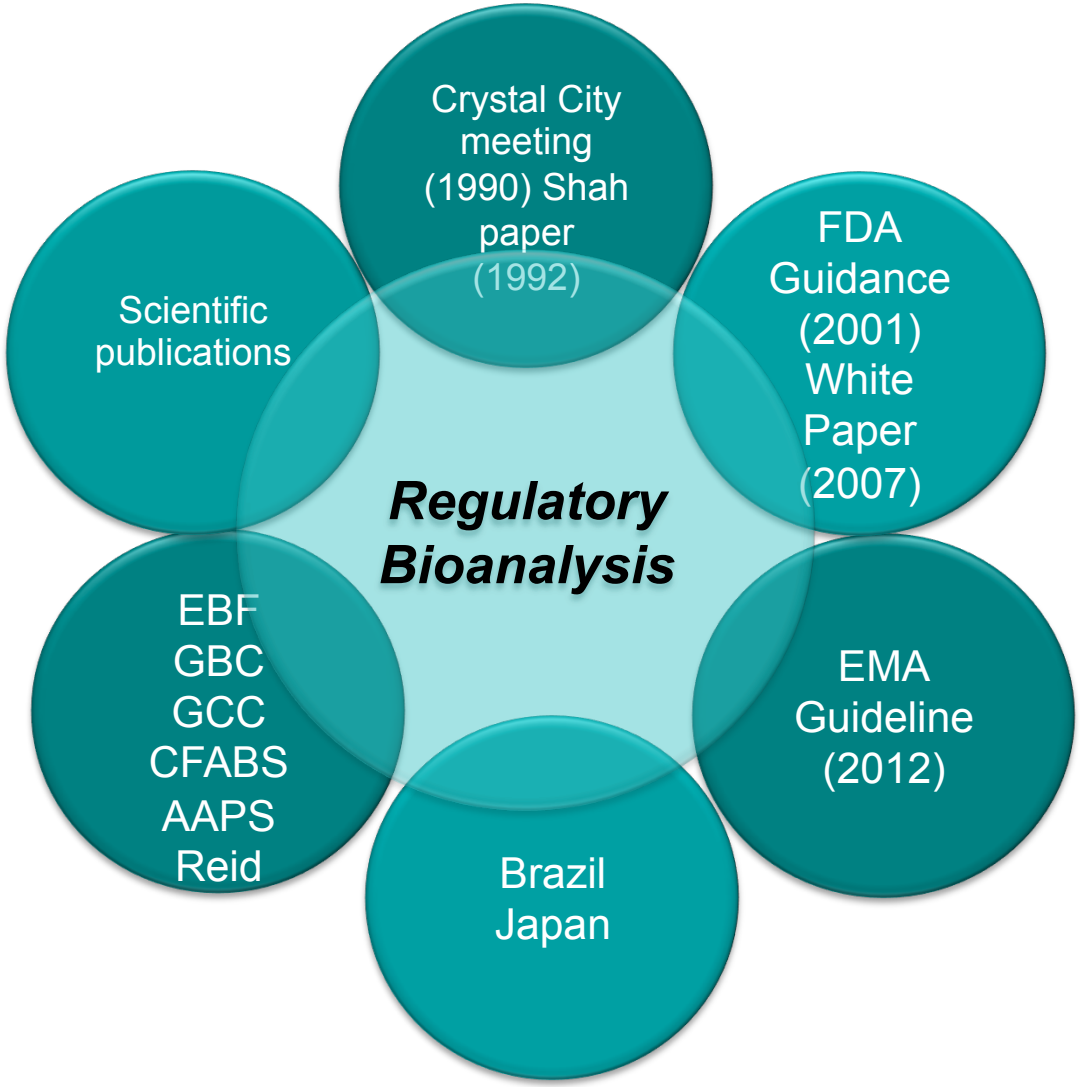
Overview

- Regulated bioanalysis – how we got here
- Impact on the way we work
- Tiered approach – challenges in a CRO
- Summary

Influences on regulatory bioanalysis



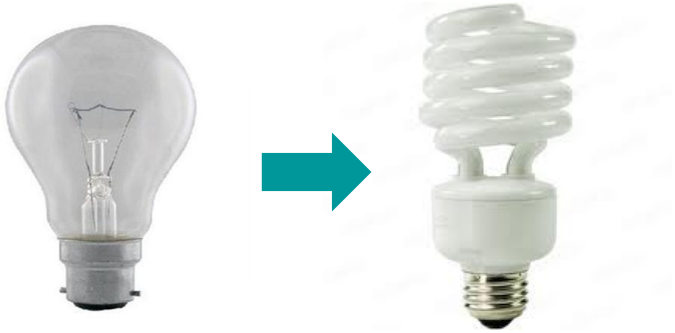
Understanding what's required

- Industry-wide consensus on regulatory bioanalysis
- Molecules move between laboratories and continents
- Don't need too much dialogue about how to do this !

US Pharma → European CRO

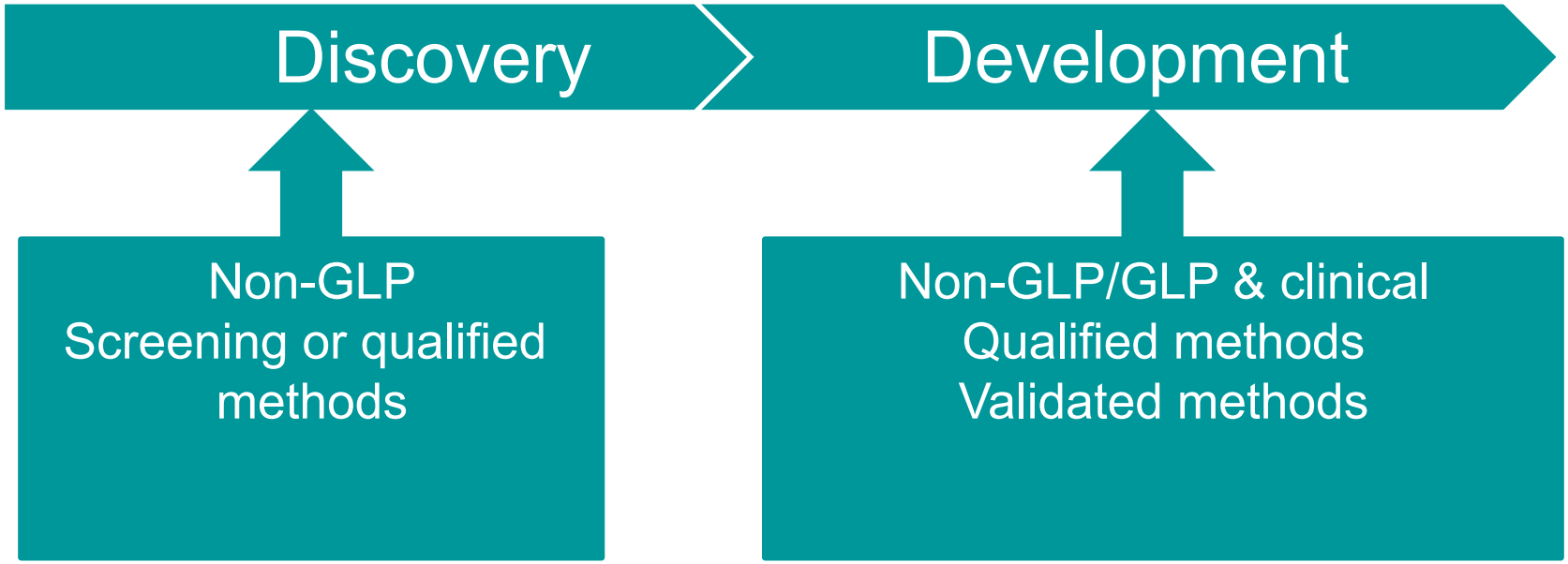
Principles of good science

- BUT….growing awareness that we need to work smarter



- “Gold standard approach” isn’t needed for everything!
- Data needs to be robust enough to meet the objectives of the study!

Tiered approach



Industry differences

- But……patchy approach across industry
- Tiered approach – alien concept
  - Metabolites in TK studies
  - Tissue methods
  - PPB studies
  - Biomarkers
  - Over engineered method validations

Tiered approach in CROs

- So what about the tiered approach in CROs?
- How is this being driven?
- CROs have a wide range of clients

Challenges implementing the tiered approach in a CRO

- Has BMV helped commoditise bioanalysis?
- Has the tiered approach introduced more variability into what we do?
- What is the impact on our data?

Programme Managers
Toxicologists
Pharmacokineticists
Clinical Units
Business Development
Clients (Sponsors)
Procurement Managers

More challenges

- Most CROs have relationships with large pharma
- Method “quality” can be set too high
- Evolutionary changes to tiered approach…….!

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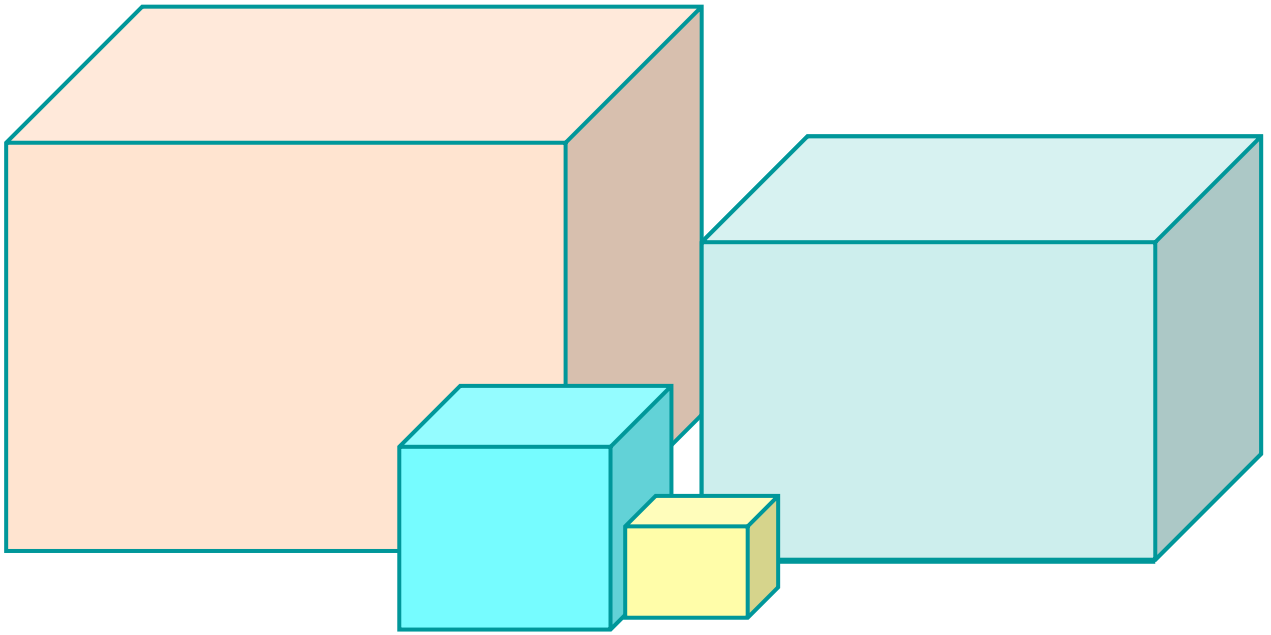

Be proactive

- CROs must develop their own approach
- Considered support from discovery to clinical
- Understand what is needed and why it is needed
- Specialists to triage enquiries

Non-Regulatory Bioanalysis

4-tiered fit for purpose approach to method qualification

Development

- Tiered approach for:
  - *In-vitro* support
  - Biomarkers
  - Tissue methods
  - Method transfers
  - Metabolites
- BMV for regulatory toxicology and clinical studies

Moving things forward

- Drug development is expensive!
- Risk of performing work to perceived lower standards than BMV?
- Build industry consensus
- More dialogue with regulators
- Raise awareness

Closer relationships

Where we are

?

Summary

- Tiered approach:
  - Sensible from scientific and resource perspective
  - Current situation makes planning less clear
  - Can be perceived as too risky
- The way forward is to:
  - Promote better industry-wide understanding
  - EBF best practice approach?
- CROs in a unique position to drive this forward

Acknowledgements

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