Enhancing internal capabilities through strong CRO-Pharma partnership

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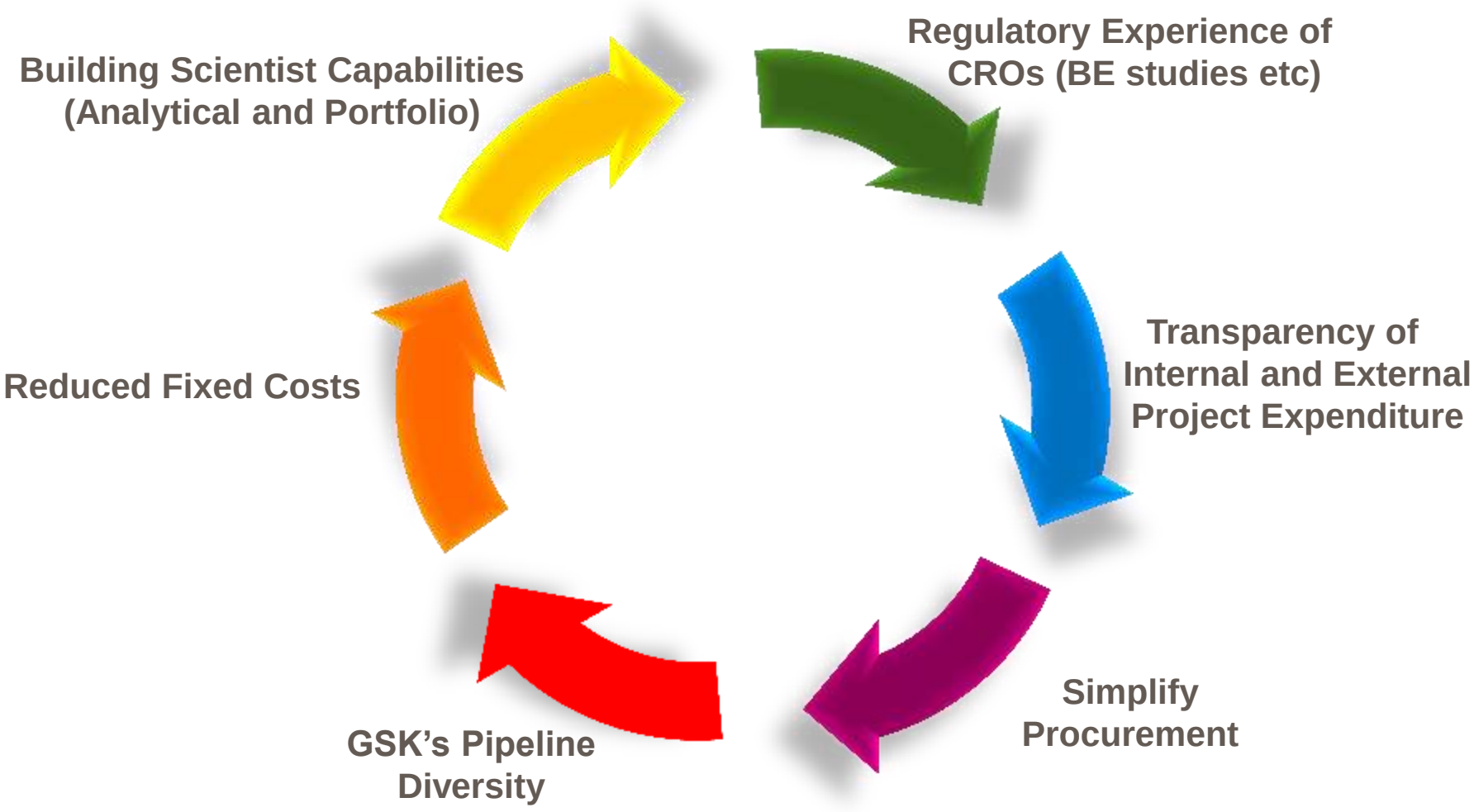
Drivers to Our Outsourcing Strategy



Where We Came From

THEN	NOW
Big Expansion in R&D 10 – 15 years ago	Greater Scrutiny on R&D Budgets
Big investment in internal infrastructure (assuming a new era in Drug Discovery) Largely based on NCEs	Reduction and control of internal fixed costs, infrastructure and capital expenditure Internal Support When An Added Benefit is Seen Drives a Continuous Improvement Mindset - Are We Still Right to Do This Work Internally?

Internal/External Balance

Discovery	**Outsource:** *In vivo* and *in vitro* screening **Internal:** PK/PD bioanalysis and investigative DMPK studies (Focus on project rep skills)
Non-GLP Tox	**Internal:** Analytical support is close to nascent project teams and can adapt rapidly to changes in project plans
GLP Tox	**Outsource:** NCE LC-MS/MS, LBA (no overt concerns from non-GLP/PK assays) **Internal:** Biomolecule LC-MS/MS, NCE/LBA where a concern has been identified
Clinical (Early)	**Outsource:** Assets acquired as licences. **Internal:** Dose escalation/iterative study designs (NCE, LBA, Biomolecule LC-MS/MS).
Clinical (Ph II to PoC)	**Outsource:** NCE LC-MS/MS and LBA. Monitor performance with KPIs, CRO visits
Clinical (late Phase)	**Outsource:** NCE LC-MS/MS and LBA. Monitor performance with KPIs

Scientist Development – Compound Expert Model

DMPK Mini-Team

Project Rep
- Host regular mini-team meetings to bring on next generation of project reps
- Share project information and strategy

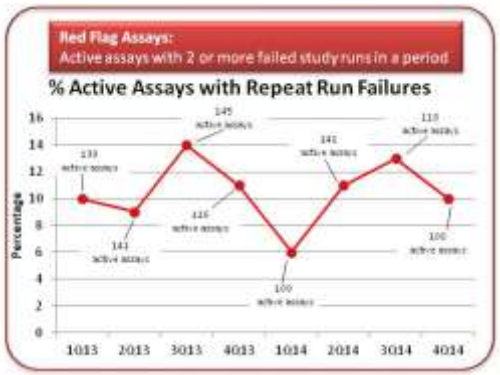
Experts
- Understand the idiosyncrasies of the compound and recommend/initiate work (e.g. interference checks, supplemental data for validation)
- Learn about other areas from internal project team environment

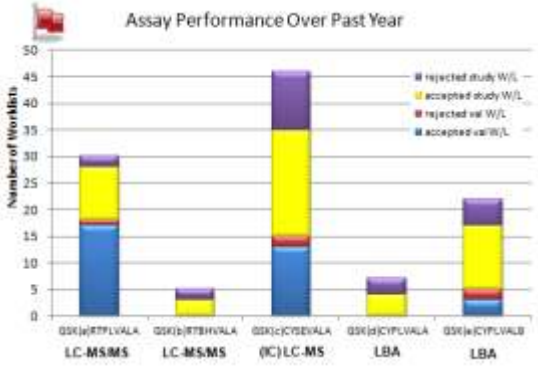
Preparing Assays for Outsourcing and Oversight

Bioanalytical External Study Monitors (BESM)

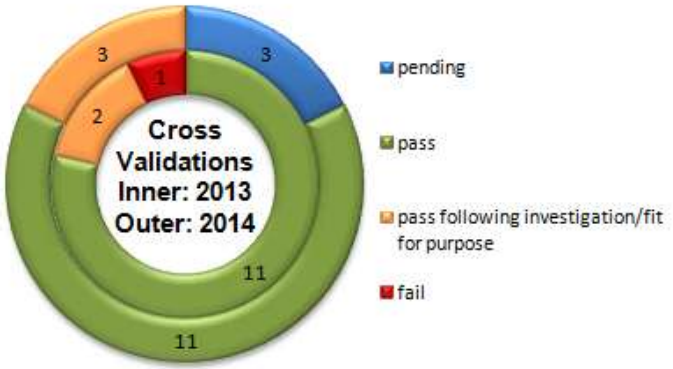
- Internal dept roles to monitor outsourced work
- Outward facing to CROs
- Monitor validations, studies and data flow
- Monitor data quality (reviews and site visits)

Internal Lead Measures
(validation and production)





Lag Measure with CRO
(cross validation)



Current Challenges Biomolecule LC-MS/MS

- Most challenging area to outsource for us.
- Technical innovations are moving rapidly
- Internal technologies are moving faster than CRO uptake
  - High Resolution Systems
  - Automated Platforms (e.g. Kingfisher)
- Large number of biomolecule assets need LC-MS/MS assays (generally multiple assays). Several false starts with CRO partners

Innovation Hurts!

- Investment in innovation and new capabilities comes at a cost (to Pharma and CROs). Pharma is incentivised by the need to deliver differentiated medicines. For CROs high sample volumes with established technologies is profitable.

- Large CROs have more resources but are they really incentivised to invest in new technologies when enough of the old business is still on hand?

- Small CROs are more flexible but do not have the infrastructure of large CROs

- Cost pressures on CROs do not help. Sponsors want to see price control but is this realistic when CROs are being asked to do more? Especially in the Biopharm area.