

Role of automation in maximizing portfolio value – the future is now

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Executive Summary

Value proposition:

- **Drive innovative scientific knowledge and technical advancement through the use of automation**
- Release scientifically and technically gifted scientists from routine processes in order to improve
 - Technical robustness, ensuring methods are capable of addressing key portfolio needs
 - Greater understanding of data generated and data interpretation
- **Improved data quality from sample integrity management through to reproducibility**
- **Improved timeliness of PK and ADA and certain protein biomarkers**
 - Capacity independent work flow
 - Capacity is based on infrastructure and IT systems rather than scientist lab time
 - Avoids resource challenges and negotiations with CRO partners
 - Significant upfront costs that lead to cost advantages long term.
- **Maximize synergies to address ever increasing needs for bio-bank and bioanalytical samples needs**

Technical improvements drives improved data understanding

Drive for more robust method development

- Release scientific staff from repetitive lab based activities in order to develop more robust methods
 - Reduce/ avoid the need for manual pipette and paper based documents (esp. validation and analysis)
 - Time focus on method development and data understanding including the ability to take on more challenging bioanalytical method
 - Improved drug and target tolerance
 - Bespoke biomarker assays including baseline assessments and longitudinal change
 - Core parameters such as selectivity investigation in different population groups, appropriate cut-point setting, statistical analysis of PC and NC levels

Improved data understanding and interpretation

- Allow scientist who develops/ utilizes the method to have greater access to project strategy
- Time spent pipetting etc. can be utilized in interpreting the data
 - Impact of preexisting immunogenicity which drives improved interact with Ab engineering colleagues
 - Robust understanding of biomarker strategy allow interpretation of data to ensure the data meets C of U

Data quality and on time data delivery

Improved on time delivery

- 2D barcode process reduces discrepancy resolution process
 - Analysis can not be initiated until all discrepancies are resolved
 - Significantly reduce discrepancy management
 - avoid 2-3 day delay in analysis planning
 - Efficiency gain: 6 hour samples processing can be performed in ca.90 seconds
- Increased reproducibility
 - Consistency of pipetting and reduction of random error is anticipated
- Analytical capacity independent workflow
 - Systems can be configured to perform analysis of 1 weeks work 1 day
 - Data quality reviewed and approved in same day
 - Efficient data upload
- Robust tracking and improved accessibility for bio-banked samples

Infrastructure requirements

Reliance on sample tube configuration and plate design

- Collaboration with Reg tox facilities and integrated CROs is key to success



Automated sample manager (-80)

- Programmable freezer capable of organizing a picking samples
- Ensure sample physical integrity and sample data management



Linked or stand alone instruments

- Incubation/ plate storage
- Robotic liquid handling via the Hamilton vantage
- Plates are moved via robotic arm
- On-line systems such as MSD or off-line such as Mass Spectrometer



Operational value

- Reduces the touch points from samples to data generation, data interpretation and project team discussions**
- Reduced need for complex legal agreements and extensive vendor negotiation on a portion of the bioanalytical work**
- Reduces the burden on vendor oversight**
- Great focus on scientific and technical consideration while reducing more routine task**
- Attrition corrected cost benefit analysis predicts break even point after 3.5 - 4 years from start**

Operating in a change culture

Transforming value from data generation to valued project insights and interpretation

Biological relevance of what we are measuring directly linked to patient value

Technology is available the greater challenge is to demonstrate the vision and development of new skills

- **What does it mean for me?**

- Changing mindset- my value is not in generating data but understanding data requirements
- Complex method development
- Confidence in platform

Where are we today

Upfront investment of 2M in CAPEX approved in 2018

Infrastructure changes have been implemented

- Lab redesign
- Infrastructure changes- air flow, BSII plus containment...

Essential equipment in place and validated

- IQ/OQ
- Instrument and IT systems validated
- Workflow validated

Workflow review completed and new workflow is fully validated for PK assays

- ADA assays to follow later this year

All ready to go for first samples!

Evolution to modern Bioanalytical lab

Summary

Greatest challenge was to give skilled colleagues a reason to believe that automation will be helpful.

- **My valued is in development of robust complex methods**
 - Drug and target tolerance
 - Answer complex portfolio questions
 - Transforming from data generation to understanding project needs
 - Regulatory requirements

Improving data quality from sample integrity management through to reproducibility

Improved timeliness of PK and ADA and certain protein biomarkers

- Less handoffs
- Improved interface between project teams and lab colleagues

Maximize synergies to address ever increasing needs for bio-bank and bioanalytical samples needs

Thanks

Special thanks to the entire TB&B regulatory
bioanalysis team

