A phase III sample analysis study: challenges and solutions

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• Background
• Proposal/contract
• Sample receipt
• Watson LIMS
• Analysis of the samples
• Reporting
• Archiving
• Concluding remarks
• Phase III study
  – 3 weeks screening phase
  – 17-week open label phase
  – 48-week double blind phase
• 1388 subjects
• Multi-center study
• 1-compound assay
• Proposal: November 2011
• Frequency of shipments: one per month per central lab site
• Batches could be scheduled on the basis of number of samples received
• Samples were received in 57 batches
• June 2012 – March 2015
• In the beginning, up to 5 shipments per month were received…
• From 2013 onwards, about 1 shipment per month was received
• For each shipment, a folder was created, containing:
  – Original shipment files
  – Watson export/import files
  – Inventory of samples
• Keep things organized....
• In total, 20641 samples were received
• 255 boxes of samples (81 each)
- Used unassigned samples
- Kept separate Excel file with all samples received:
• In this Excel file add:
  – Date + Time
  – PRA Box number plus position in box
  – Date samples received at PRA

• Concatenate new Sample ID:
  – Accession number_Subject ID_Visit_Box number_position

• Paste this into Watson

• This information also appears on Work List

• Technicians would keep in a separate file which boxes were analyzed in which run
• Performance of Watson LIMS slower and slower…
• After 15000 samples analyzed, almost impossible to work with
• Created another study in Watson, described in Note to File
• Sponsor agreed to have summary statistics for entire study split in two parts
• Meanwhile upgraded to Watson 7.4.2: better performance
Analysis of the samples

• 140+51 = 192 runs (of which 4 qualification runs)
• 1 run not started because of a preparation error
• No rejected runs
• No ISR done (already done in patients with this method)
• In two runs problems with dilution QCs
• Results very tight:
## Analysis of the samples

### Calibrators part 1:

<table>
<thead>
<tr>
<th></th>
<th>0.101</th>
<th>0.198</th>
<th>0.493</th>
<th>2.04</th>
<th>5.05</th>
<th>20.0</th>
<th>49.3</th>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>%CV</td>
<td>2.7</td>
<td>5.6</td>
<td>4.0</td>
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<td>3.1</td>
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<tr>
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<td>-1.4</td>
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Analysis of the samples

- Calibrators part 2:

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<tbody>
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<tr>
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<td>0.0</td>
<td>0.0</td>
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<td>-1.0</td>
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<td>51</td>
<td>51</td>
<td>51</td>
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</tr>
</tbody>
</table>
• Data reported on time
• Reconciliation done: Excel file with >600 ‘inconsistencies’
• Excel file with all shipments sent
• Only 7 changes to identifiers were requested; documented in a note to file.
• A report with 1861 pages was written
Archiving
Archiving
Concluding remarks

- Important to state upfront expectations towards shipment frequency
- Keep things organized per shipment
- Use unassigned samples in Watson LIMS
- Keep separate Excel file with all shipments
WE ARE DEDICATED TO THE FUTURE OF CLINICAL DEVELOPMENT AND TO EVERY LIFE IT SAVES.