

Automation using SAS

&

C#.NET

PhUSE 2009

Basel

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- **Automation - What? Why? When? How?**
- **Clinical Trial Processes**
- **How to automate – Clinical Trial Processes ?**
- **Case Study**
- **Demonstration**



- **What ?**

Process automation involves using computer technology and software engineering to help Clinical Research & Development process in Drug Discovery division of Pharmaceutical operate more efficiently and meeting regulatory requirements.

- **Why ?**

- **Saves time & effort**
- **Improve productivity**
- **Improve operational efficiency**



- **When ?**
 - Repetitive tasks
 - Repetitive tasks with minor variations

- **How ?**
 - Using validated technology that is prevalent today



- Data Extraction from data capture systems
 - EDC, Excel, ASCII, XML,
- Cleansing & Analysis (Derivations)
- Biostatistical analysis
- Report generation (listings, tables, graphs)
- Clinical data standards (CDISC)
- Submission preparation (eCTD)
- How each process are interconnected -- through a diagram



- <Diagram will be pasted here>



- Understand the processes to be automated
- Map & use appropriate technology
- Identify the processes to be used
 - Prototyping & risk assessment
 - Standards to be followed
 - Development
 - Validation
 - Documentation



- Use iDERT as an example
- Automated the complete source to submission process – Extraction, Cleansing, Analysis, Biostatistical analysis, CDISC, eCTD M5 preparation
- Technology used
 - SAS, C#.NET
- Performed prototyping of integration points
- Adopted GAMP CAT5 model



- Ultimate benefits
 - Reduction in turn around time
 - Improve productivity
 - Improve operational efficiency
 - Implementation of consistent quality
 - Availability of Clinical Integrated Data Repository (CIDR)
 - Ease of traceability & regulatory compliance



Scope covers the complete demonstration of automation from Source to Submission preparation in iDERT



Q & A



Thank You

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