INTRODUCING CLINIC AUTOMATION IN A PHASE I UNIT WITH END-TO-END E-SOURCE DATA PROCESSING

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PhUSE Conference 2014

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WHEN YOU NEED TO BE SURE

SGS

OUTLINE

- What is Clinical Automation?
- Why we implemented an clinic automation system?
- Scope of the clinic automation system
- Implementation overview
- Key Benefits
- Benefits for Data Management
- Experiences from monitors & clients
- Encountered challenges
- Take home messages

WHAT IS CLINICAL AUTOMATION?

- A centralized software tool implemented within a clinical unit to:
  - support the recruitment of volunteers
  - directly capture study data electronically (eSource)
  - streamline the clinical process

- Allows sharing online, real-time, high quality data with clients

WHY IMPLEMENT AN AUTOMATED SYSTEM?

CLIENT NEEDS

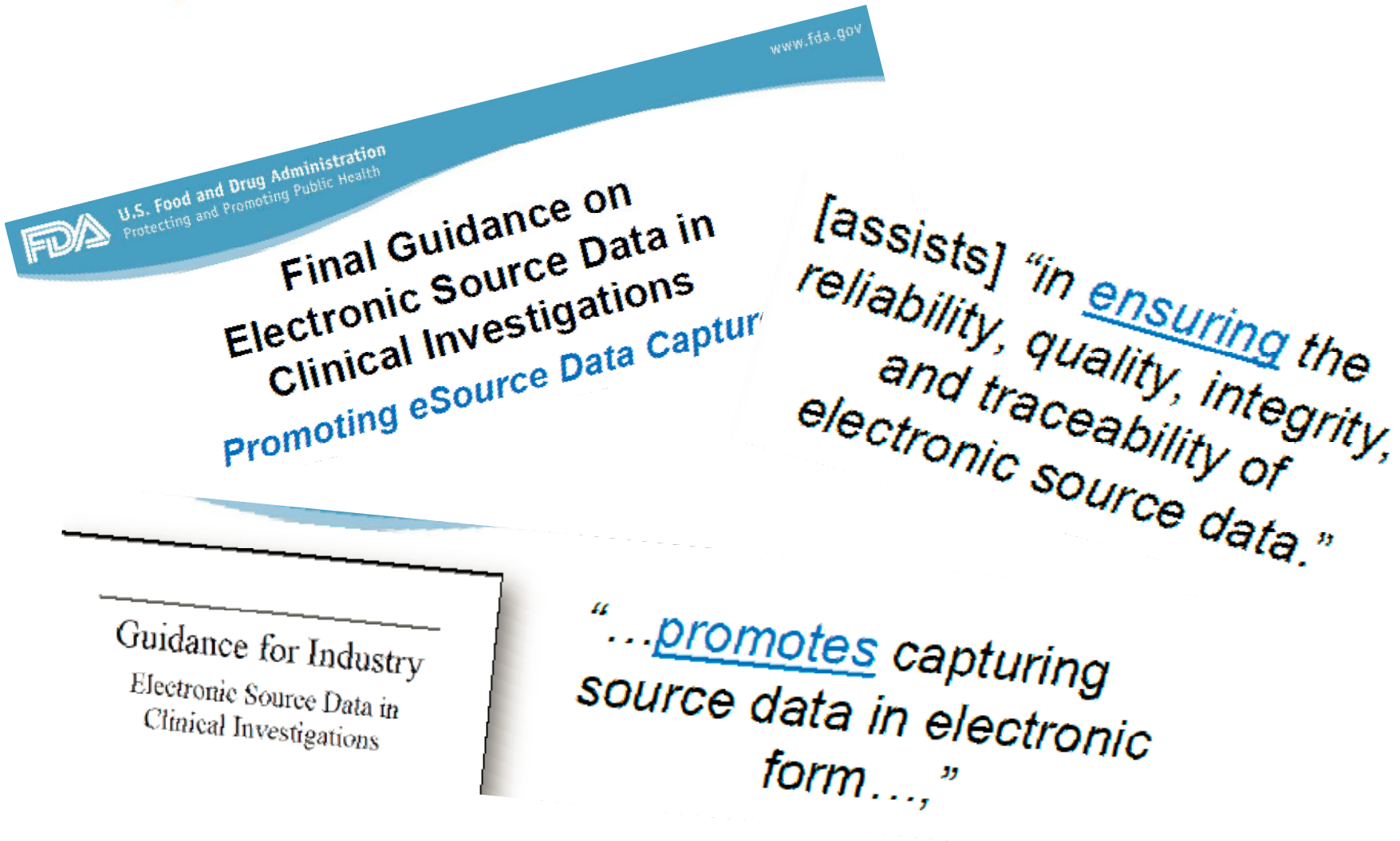
- Clients indicated the need for an EDC system
  - Main drivers for our clients are:
    - Time and Cost-saving
      - Paperless e-crf
      - Quick set-up and recruitment
      - Single data entry instead of double data entry
      - Simplified and remote monitoring
      - Reduction of queries
    - Remote access to online, real-time, high quality date
    - Traceability
      - From eSource to electronic regulatory submission
    - Quality

WHY IMPLEMENT AN AUTOMATED SYSTEM?

ENCOURAGED BY REGULATORY AUTHORITIES

- References:
  - Oversight of Clinical Investigations – A Risk-Based Approach to Monitoring - U.S. Department of Health and Human Services - ***Food and Drug Administration***
    - ***FDA Webinar – Jan 29, 2014***
  - The final FDA guidance of Aug 2013
  - The future integration of Electronic Health Records (EHR) and the finalization of the ICH E2B(R3) standards will provide an end to end solution for one overall integrated approach on patient safety monitoring.
  - Reflection paper on expectations for electronic source data and data transcribed to electronic data collection tools in clinical trials – ***European Medicines Agency***
  - Oversight of Clinical Investigations – A Risk-Based Approach to Monitoring - U.S. Department of Health and Human Services - ***Food and Drug Administration***
  - Computerized Systems Used in Clinical Investigations - U.S. Department of Health and Human Services - ***Food and Drug Administration***
  - CDISC e-source standard requirements-CDISC (Clinical Data Interchange Standards Consortium) Version 1.0 20 November 2006

SNAPSHOTS FDA WEBINAR – JAN 29 2014



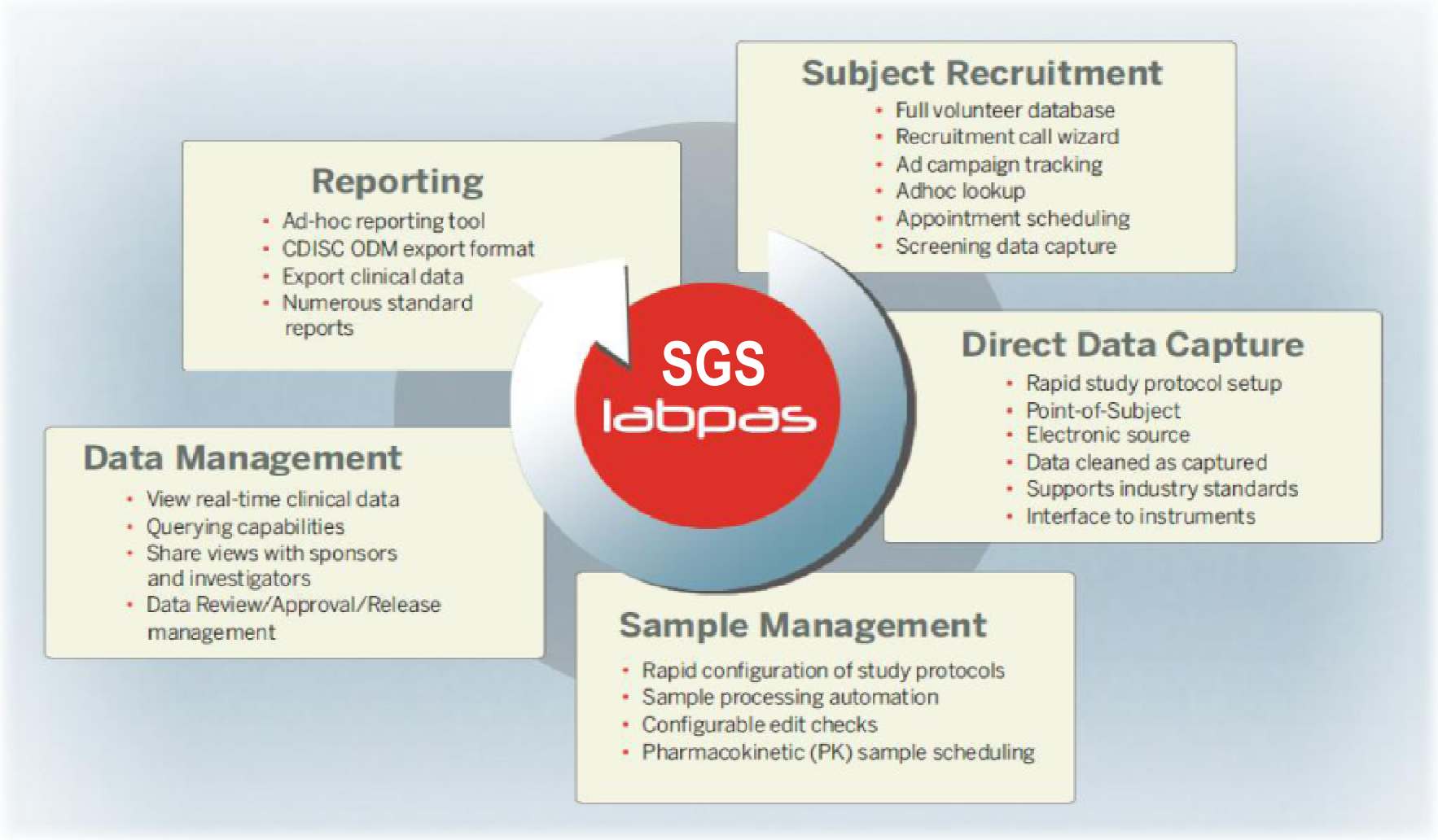
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM328691.pdf

WHY IMPLEMENT AN AUTOMATED SYSTEM?

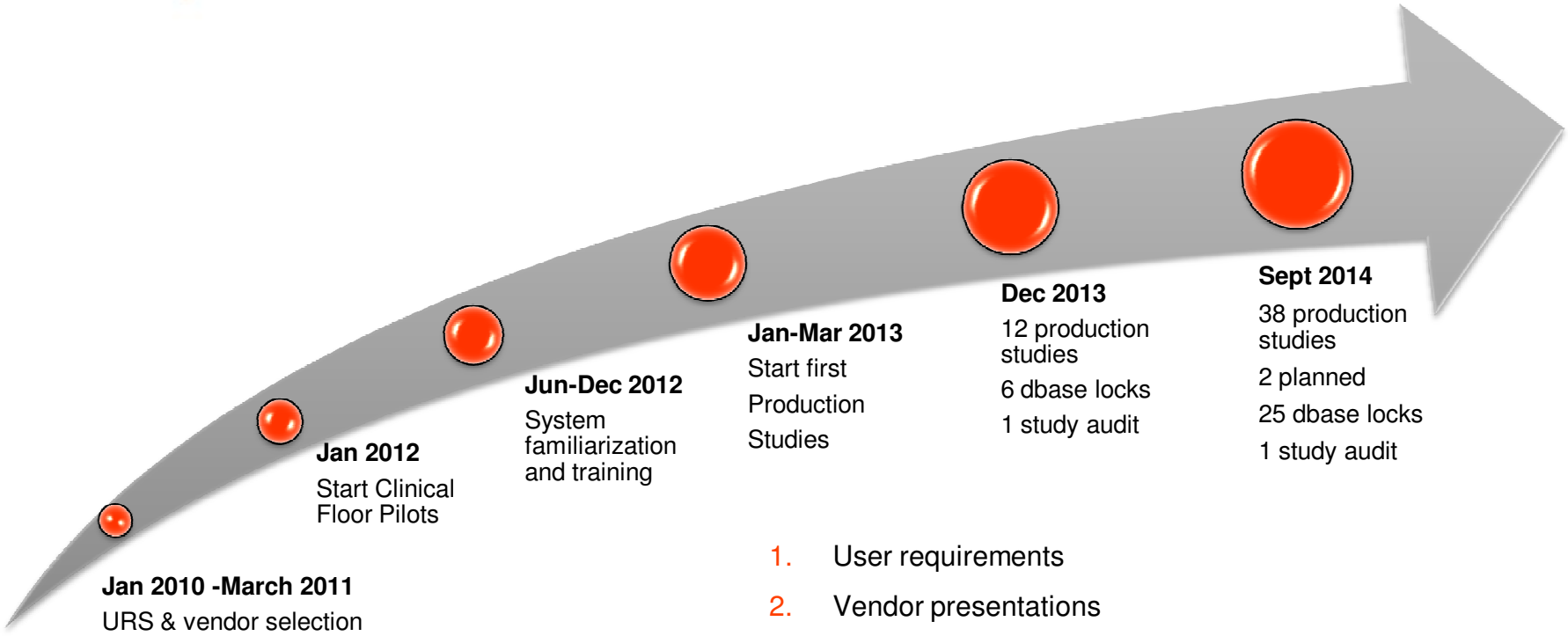
OPTIMIZE THE CLINICAL PHARMACOLOGY UNIT'S PROCESSES

- Running multiple trials at a single location and staffed by a common group makes a Phase I unit a natural setting for automated solutions
  - Supports subject management / selection / appointments
    => faster recruitment
  - Automates the workflow through an electronic trial design schedule driving key operations at the clinical floor (what /where/whom/when)
  - Collects real-time source data electronically
  - Controls the sample management process
  - Enables sharing of online, real-time subject clinical data to review and process
  - Supports query management
  - Supports study and resource planning

SCOPE OF THE CLINIC AUTOMATION



IMPLEMENTATION OVERVIEW



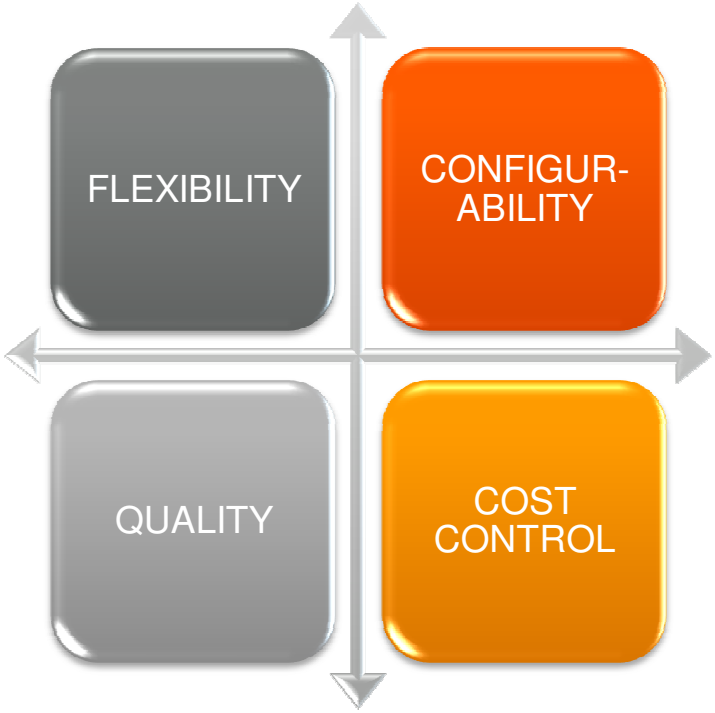
1. User requirements
2. Vendor presentations
3. System evaluation life situation
4. Vendor selection
5. Setup IT infrastructure
6. End-user training
7. Conference Room Pilots
8. Clinical Floor Pilots
9. Go live

STUDIES PERFORMED WITH LABPAS IN ANTWERP



	Locked	Ongoing	Planned	Total
Full scope projects	12	10	2	24
With partial data transfer	4	1	0	5
As source only	9	2	0	11
Total	25	13	2	40 23 different clients

LEVERAGING THE CLINICAL PROCESS



SUBJECT RECRUITMENT → PROTOCOL SETUP → STUDY EXECUTION → DATA CAPTURE → SAMPLE MANAGEMENT → DATA MANAGEMENT → REPORTING

WHAT ARE THE KEY BENEFITS? 1/4

SUBJECT RECRUITMENT

- Quicker recruitment
  - An easy-to use scripted data collection wizard and appointment scheduling tools
  - An efficient configurable inclusion & exclusion rules process (demographics & medical history)
  - Integrated trigger for payment subjects

PROTOCOL SETUP

- Rapid protocol setup
  - Days instead of weeks compare with eCRF set-up time in an EDC system
  - Libraries with adaptable elements (test panels and tests)

STUDY EXECUTION

- Screening / Study execution
  - Follows operational workflow of nurses/lab technicians
  - Provides “what, where, whom and when” info they require to run the trial
  - Wireless solution to increase the mobility of the nurses

WHAT ARE THE KEY BENEFITS? 2/4

DATA CAPTURE

- Direct data capture strongly reduces the need for paper
  - Direct data capture from devices (no human intervention)
  - Device interfaces with HL7 as promoted by FDA
  - Barcode driven (subject, dose, collection, instruments) which increase data quality
  - Edit-checks and alerts reduce data entry errors
  - Transcription eliminated



SAMPLE MANAGEMENT

- Automated sample management
  - Barcode-driven sample management captures data and controls samples process
  - Automated lab data integration (hospital lab for safety samples)

WHAT ARE THE KEY BENEFITS? 3/4

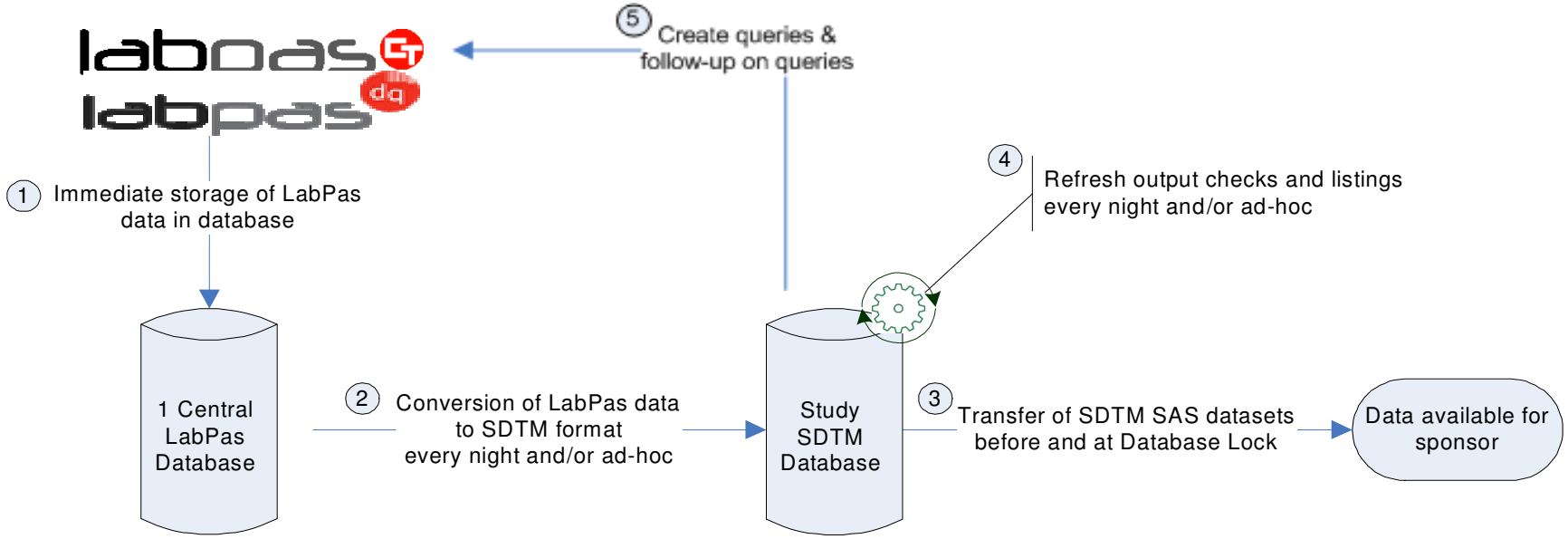
DATA MANAGEMENT

- Optimized data management
  - eSource system as eCRF platform
    - Eliminating (e)CRF design
    - Data visualization & verification, review and approval with metrics
    - Query management
  - Flexible data transfer options
    - Different data transfer options available
      - CDISC SDTM datasets
      - CDISC Operational Data Model (ODM) extract
      - Custom sponsor data format
    - Online access to subjects data (sponsor access)
  - Real-time subject data monitoring allows faster query resolution

REPORTING

- Comprehensive Reporting

DATA FLOW


labpas
dq
labpas
5 Create queries & follow-up on queries
1 Immediate storage of LabPas data in database
4 Refresh output checks and listings every night and/or ad-hoc
1 Central LabPas Database
2 Conversion of LabPas data to SDTM format every night and/or ad-hoc
Study SDTM Database
3 Transfer of SDTM SAS datasets before and at Database Lock
Data available for sponsor

BENEFITS FOR DATA MANAGEMENT 1/3



- The setup of LabPas studies will be standardized per sponsor:
  - Library screens used in LabPas
  - Standard CRF template
  - Standard CRF annotation
  - Standard conversion rules
  - Standard DVP including rules
- This will lead to a more efficient process, which will save time and money.

BENEFITS FOR DATA MANAGEMENT 2/3



- Data cleaning can start earlier
  - Cleaning can start as soon as clinical data is captured in LabPas
  - LabPas data immediately available for DM for import into clinical database
    - No data extracts needed
  - No additional monitoring time needed
    - Monitoring queries can be raised in parallel with cleaning
  - Limited source verification
    - Monitoring can be done remotely
  - Database lock will be earlier
- Turnaround of the queries is shorter
  - All queries created in the DQ module of LabPas are directly seen in the CT application of LabPas
  - Through online process the query response time is reduced

BENEFITS FOR DATA MANAGEMENT 3/3



- Number of queries decreased – improved quality of source data
  - System queries run first in the LabPas application flagging all possible anomalous data
    - E.g. values out of ranges without investigator evaluation, missing comments when a test is not done,…
  - Elimination of data entry or transcription errors to a minimum
  - Less missing data
    - System requires a comment when a result is not captured
  - Lab results automatically loaded into the LabPas system
    - No additional data transfers needed
- AE and CM terms standardized, based on MedDRA and WhoDrug
  - Facilitate coding

IMPROVING TIMING

TIME

- Standard forms and work-flows enable setting up of studies faster
- Automated labeling of vessels
- Saving time to respond to queries through online process
- LabPas architecture using one database structure to store data for all studies allows reports or data management sponsor templates from one study to be used for other studies improving synergies

COST & QUALITY

- Automation of manual processes reduces errors in data capture and improve adherence to protocol; automated process are both on the clinic floor and during PK sample processing
- Real time reporting enables quick corrective action, where necessary
- Automation of results capture, data entry etc. will reduce paper and stationary required
- Significantly fewer errors and queries through real time checking and more controlled process
- Receiving the data in already edit-checked electronic form

AUDIT & COMPLIANCE

- Enables tracking adherence to protocol
- Audit control records fully captured in the central database
- Maintains protocol versions
- ~20 standard reports in LabPas that can be leveraged out of the box
- Easy to make customer reports as well
- Role specific dashboard

IMPROVING COST CONTROL & QUALITY

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IMPROVING AUDIT & COMPLIANCE

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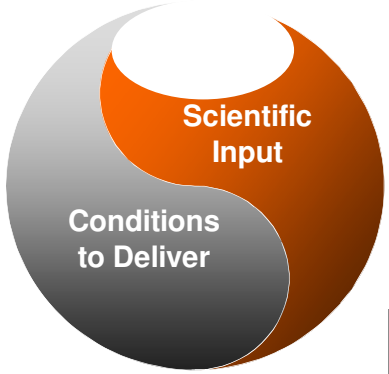
EXPERIENCES FROM MONITORS AND CLIENTS

- *The availability of tabular excel reports is successful*
  - *Daily refresh of reports on sFTP server*
  - *Standard reports available but can be customized per client*
  - *1 client reduced monitoring time with 45% after learning curve of 2 weeks.*
- *A lot of checks can be done at home/in the office (so travel hours reduction and flexible work planning)*
- *Source data is always available. If confirmation is needed about something, you don't need to go to the site to double check*
- *There are alerts if values are out of range => increased quality*
- *There are excel files to filter data, which makes it possible to check the data as wanted. F.i. per assessment instead of per subject.*
- *No mistakes/time wasted due to unclear handwriting*
- *High quality SDTM datasets available throughout the trial*

CHALLENGES ENCOUNTERED

- Internal learning curves may be longer than expected
- Implementation needs to be supported by SOPs/WIs
- Learning curves within sponsor companies as well
  - Implementation of a clinic automation system influences the structures and processes of sponsors
  - Sponsors worry about the steep learning curves to switch to the clinic automation system despite the advantages
- Some technical limitations encountered => new release by Oracle

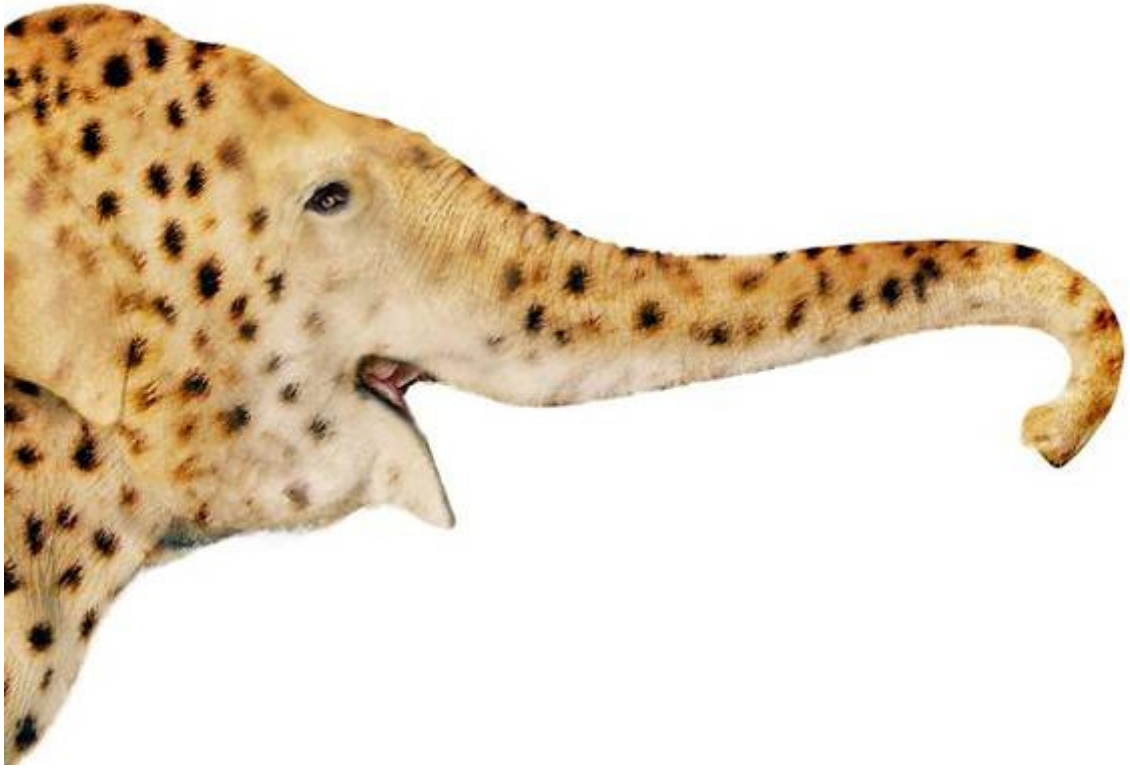
TAKE HOME MESSAGES



- Choice to implement was driven by
  - Our clients first
  - Authorities such as the FDA & EMEA are promoting EDC
  - Need to streamline the clinical process
- eSource allows remote (risk-based) monitoring
- Multiple benefits at Data Management level
- Increased quality and traceability
- Big, Medium & Small pharma do like the system and our approach

➔ CLIENTS & SGS ARE IN A WIN-WIN POSITION

THANK YOU FOR YOUR ATTENTION



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