

Harmonizing SDTM at the Source: Designing Collection Instruments that Support Sponsor Standards

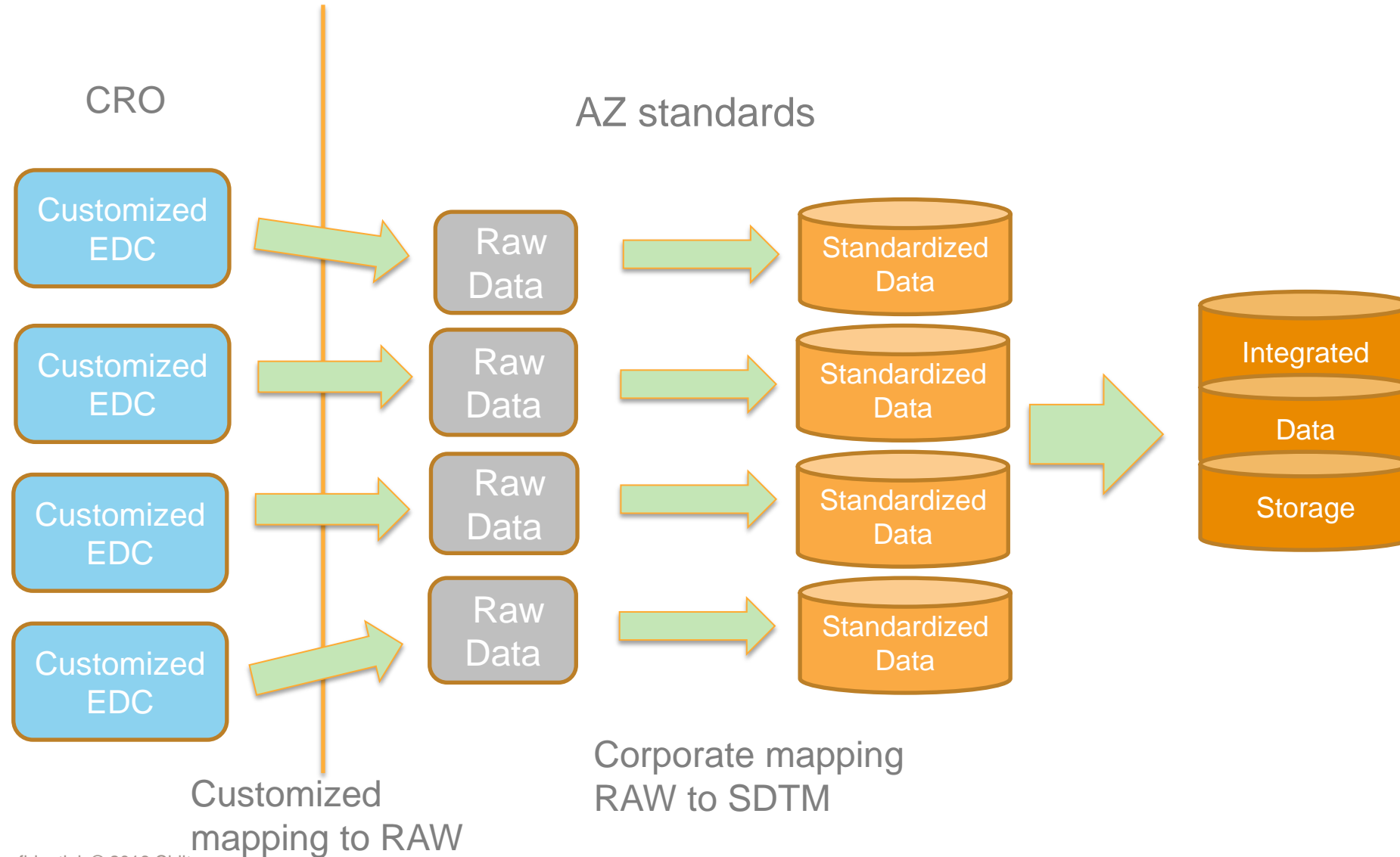
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- Introduction
- Current Model
- New Model
- Progress so far
- Tips and Hints
- What the future looks like?

- AZ Overall operational goal is to ‘Get Closer to the Data’
 - Focus on best practice for Early Clinical Development (ECD)
- AZ / Chiltern International entered into a partnership agreement
 - Data Management / Analysis and Reporting (A&R)
 - Shared responsibility and accountability at all levels
- Proposed working Model
 - Chiltern to provide core DM and A&R tasks
 - AZ to perform adhoc tasks
 - AZ / Chiltern team members to ‘sit alongside’ on clinical study teams

Current Model



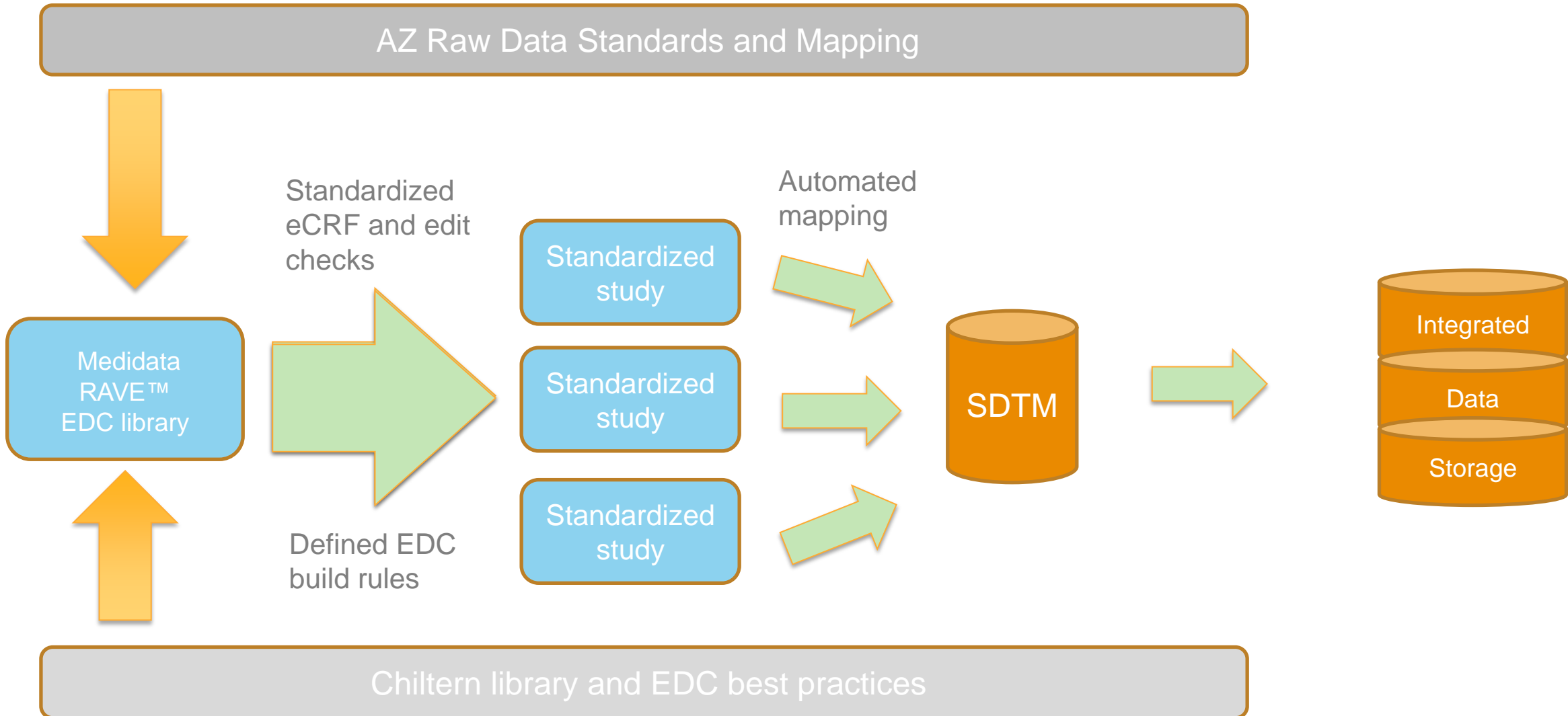
- Standardized at the RAW to SDTM mapping level
- CRO provides SAS datasets compliant to RAW data standards
- CRO given flexibility to build at the EDC level
- Can lead to variation at the EDC level
- Focus away from the data collection end and investigator experience

New Proposed Model



- In order to meet the AZ operational goal ‘Get closer to the Data’, the following objectives were set:
- Focus on EDC design and investigator experience, making the best use of technology
- Automate mapping to SDTM where possible
- Stay within the bounds of corporate AZ SDTM standards and processes
- Underpinned by the Partnership philosophy and a Joint Governance model

New partnership model



- Joint AZ / Chiltern (CIL) Standards Governance Team established to manage ECD standards
 - Bi-weekly meetings
 - Approve local level requests
 - Track AZ Standards requests

Objects not already part of AZ standards

Approves any changes or additional fields that are already in AZ standards

Can select optional fields, modify allowable codelists



AZ Standards

AZ/CIL ECD Team

Study Team

Standard AZ practice

CDM & Biometrics representatives

Includes AZ/CIL team members

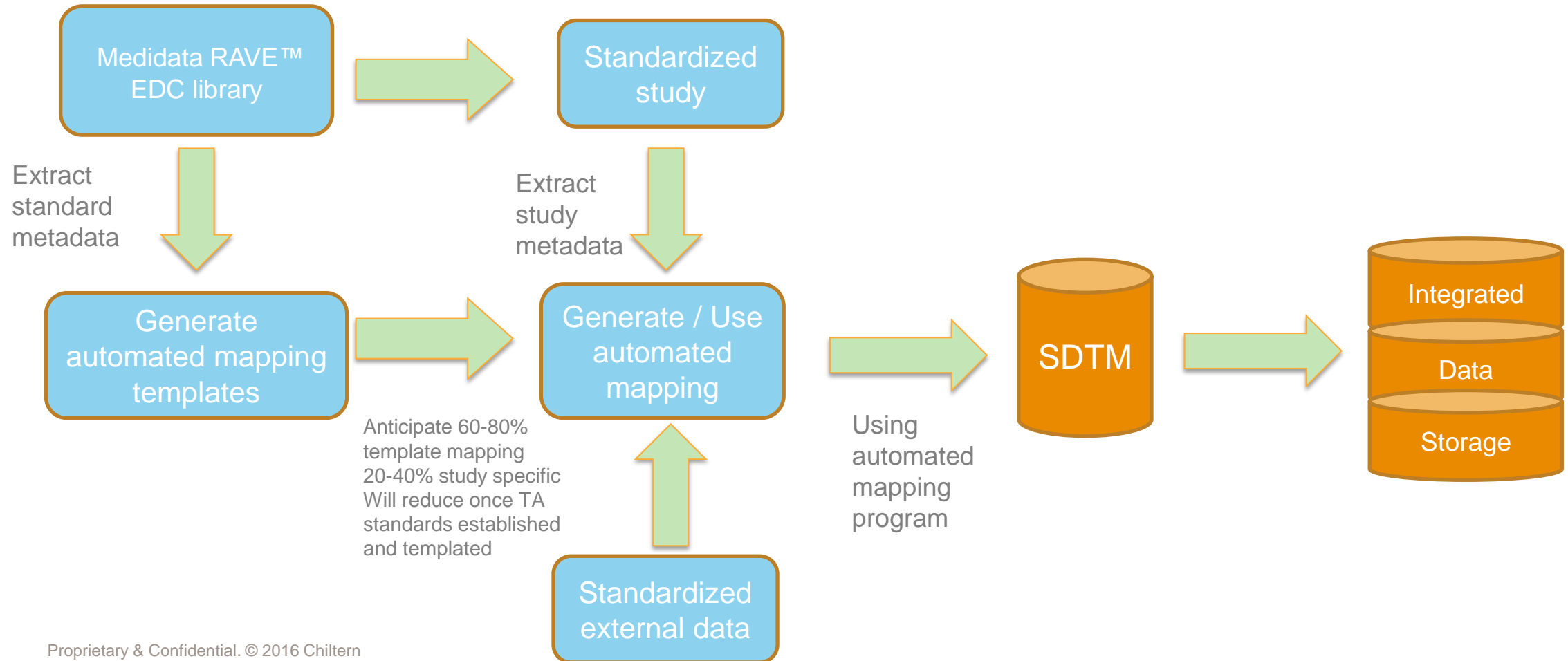
- Broaden the scope of standards to include EDC standardisation, fully end-to-end:
 - EDC build rule definition
 - Visit naming / scheduling
 - Edit checks
 - EDC form visibility rules and dynamics
 - Integration definition
 - EDC reporting

- Development of tools to be used to assure compliance to standards.

- Core set of Cross-TA Forms plus edit checks agreed and built
- Defined Visit structures – visit names, unscheduled visits
- EDC best practices defined
- Integrations defined and agreed
- Governance process defined
 - AZ/CIL team established
 - Defined end to end standards approval process
- Trialing automated SDTM mapping generation

Automated SDTM mapping

AZ Raw Data Standards and Mapping



- Define training material as you go
- Joint training, by study team, following partnership philosophy model
 - Developed jointly
 - Chiltern and AZ trained side-by-side
 - Detailed process training provided / repeated / recorded
 - Quick Reference Guides
 - 1 page documents – support for new staff or reminders
 - Support process rollout and embed
 - Facilitate consistency across studies from both AZ and Chiltern
- Implement a Hypercare model
 - Ensure change leadership is engaged at the study level
 - Rapid feedback to resolve any roadblocks the study teams may face
 - Include standards representatives – avoid the ‘Ivory Tower Standards Model’

- Study timelines
 - Responding to changing timelines
 - The first expected study changed
 - 5 initial studies identified – overlapping FSI's
- Resources from wider groups outside of ECD
 - E.g. safety and integration team
 - Share information as early as possible
 - Learning, try to onboard those groups very early in the process already at contract stage
- Recruiting in a timely manner
 - Allowing for recruitment and onboarding time

What the future looks like?



- Standards - Process and Governance
 - Improved study setup timelines
 - Re-use of standards
 - Familiarity of study teams to standards and process
 - Focus on new/novel objects rather than standards
 - Reduce review cycles
 - Expanded standards
 - Include TA standards to support ECD studies
 - Evolve based on feedback, lessons learned, Industry best practices
 - Support SLA collection
 - Metrics – how standard?
- Continued focus on ECD studies
 - Including the best use of EDC software – taking advantage of new functionality
- Support Partnership Model/ Get Closer to the Data

Thank You!!!



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