



Delivering eSubs in Light Speed

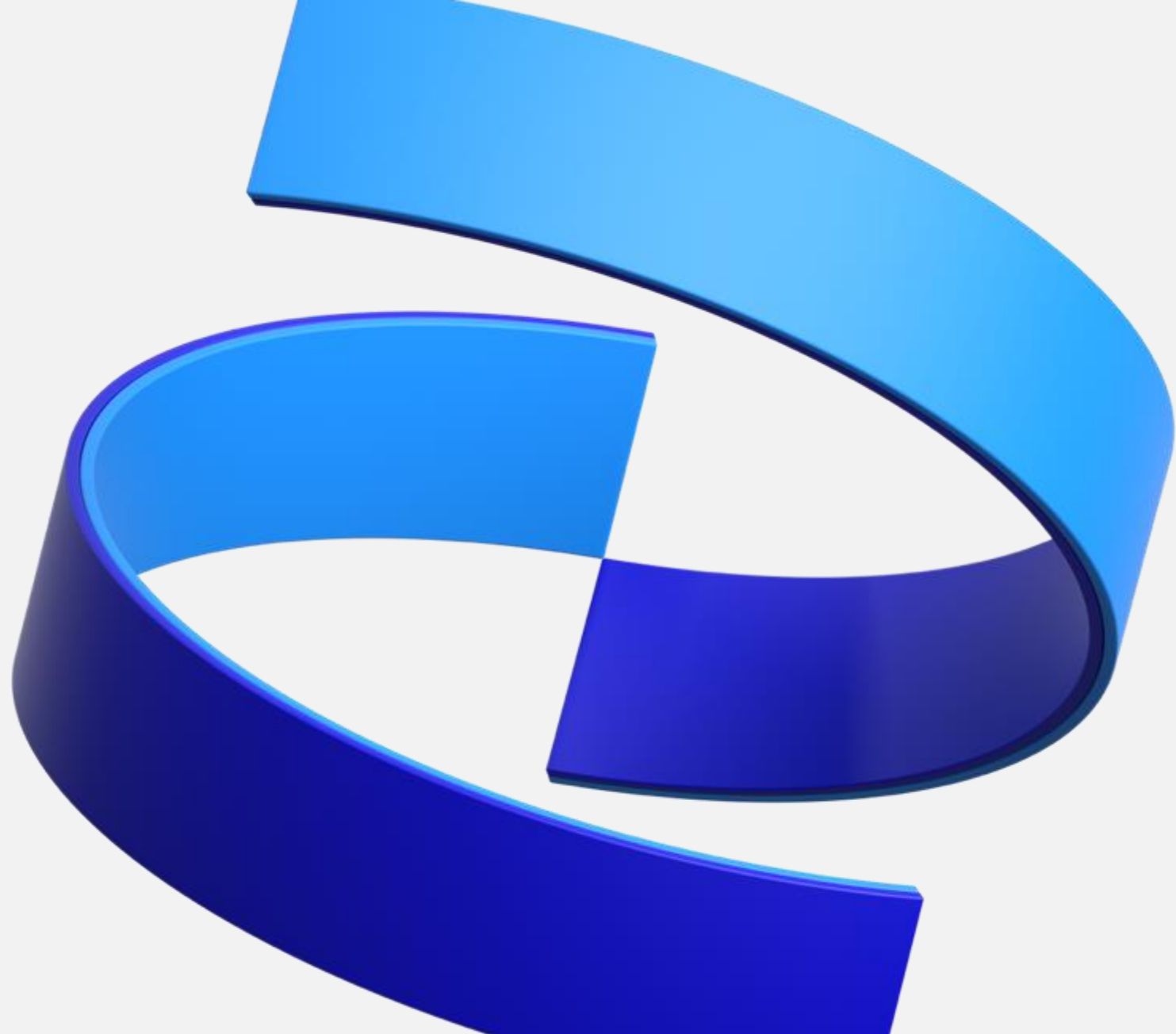
Making the Impossible Possible

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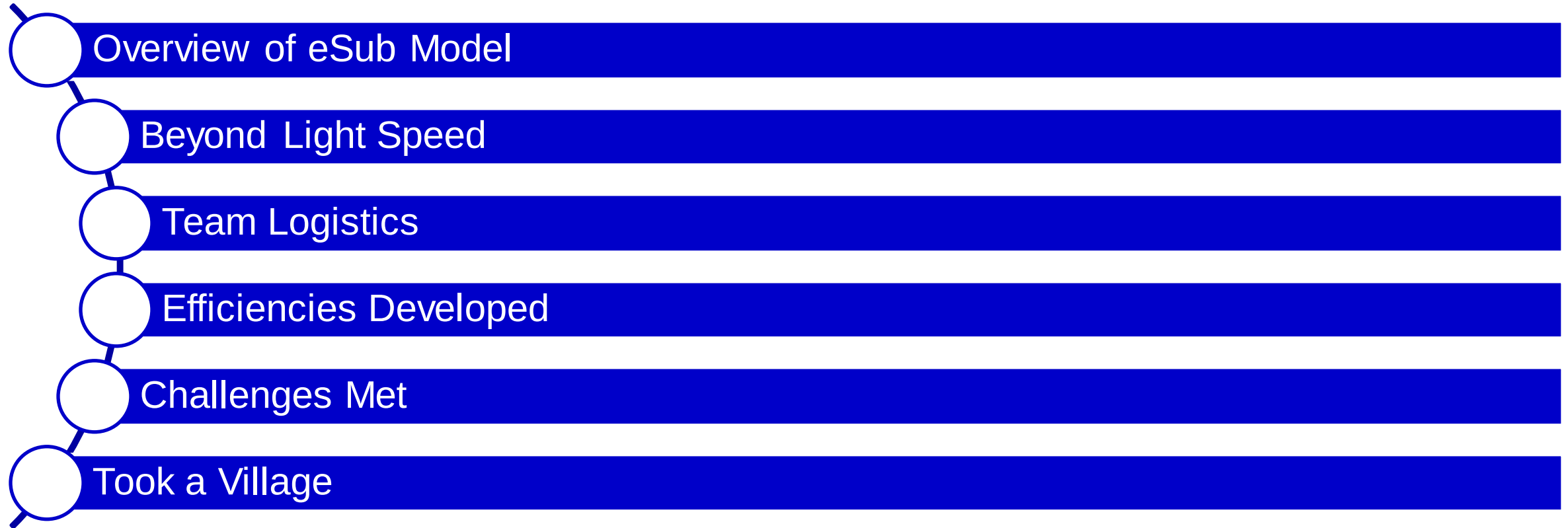


Disclaimer

This presentation is for education purposes only and should not be construed as an endorsed standard of operation for every company. We may discuss the several factors or standard operating procedures that we follow that have enabled the processes to be effective in generating quality deliverables.



Overview



Overview of eSub Working Model

1. Typical eSub timeline

- Planning begins 12-18 months ahead -- data packages developed in months per study
- Work done by study team

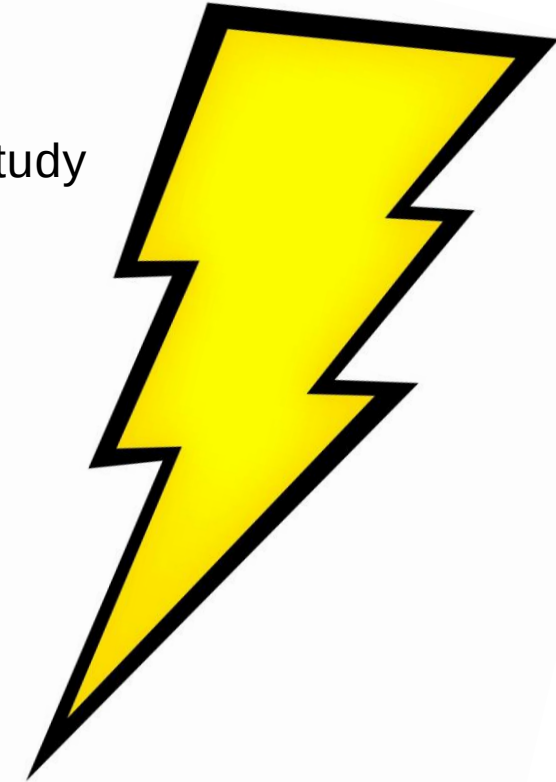
2. COVID-19 Vaccine Landmark Submission Delivered in Record Time

3. Internal Review of Processes

- Evaluated process changes that enable delivering quickly; efficiencies identified
- If it can be done for one, it can be done others

4. Light speed working model established

- Only for top priority work
- Work done in days and weeks
- Dedicated eSub data package build team working in tandem with study team





Overview of Light Speed Programs

Top priority Submissions

1. Initially four programs across three therapeutic areas identified
2. Two programs in vaccines
3. Light speed deliveries from vaccines in 2022:
 - 22 submissions
 - 43 studies
 - 158 data packages -> average of **13 per month or 3 per week!**

Beyond Light Speed – First Month of 2022 – Vaccine Program

Not a typical complexity

15 eSubs in 1 Month (7 delivered in 2 weeks)

	Number
eSub Data Packages Total	28
Total Deliverables	~540
XPTs	399
Defines	28
DRGS	28
QC & Approval Documents	82
Data Subsets	7
Cutoff Dates	6
Snapshot Dates	4

Data Package Type Breakdown

SDTM

- XPTs = 319
- Define = 13
- cSDRG = 13
- aCRF = 3

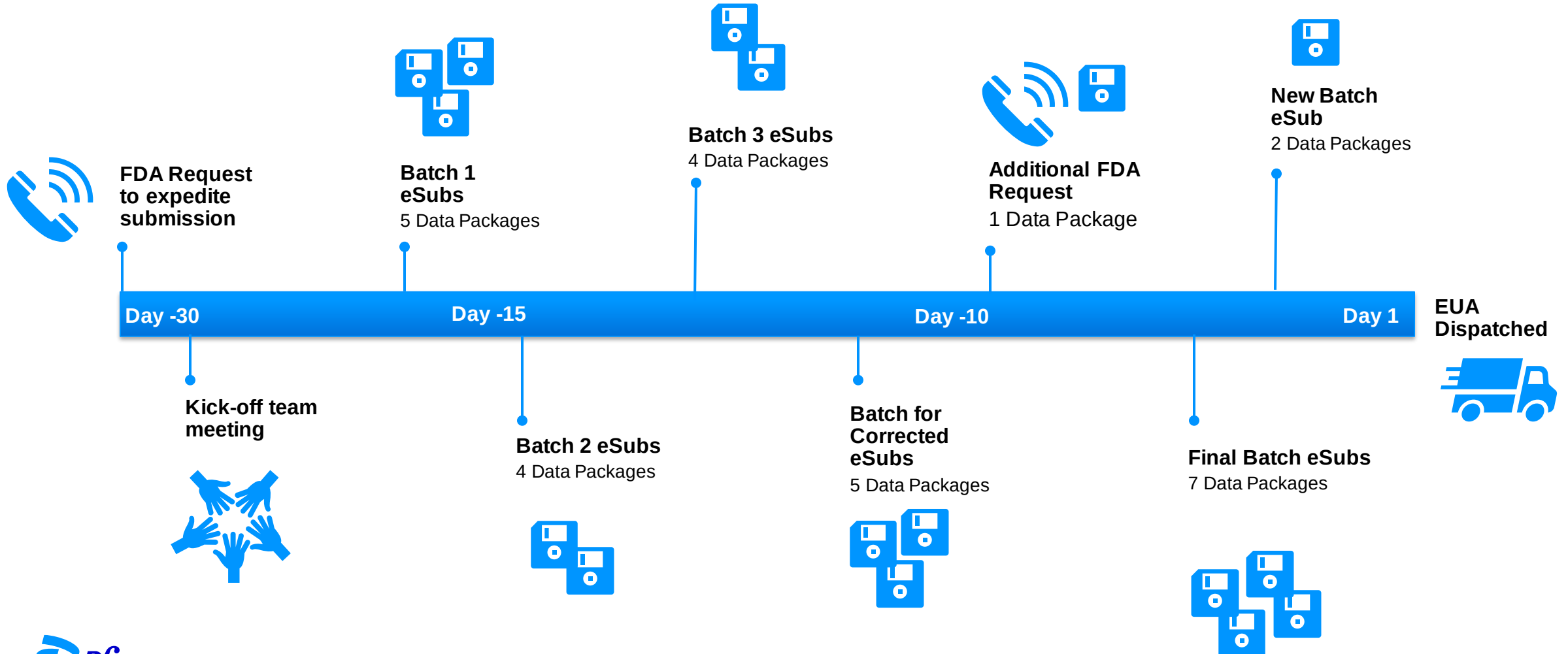
ADaM

- XPT = 80
- Define = 15
- ADRG = 15

QC & Approvals Docs = 82

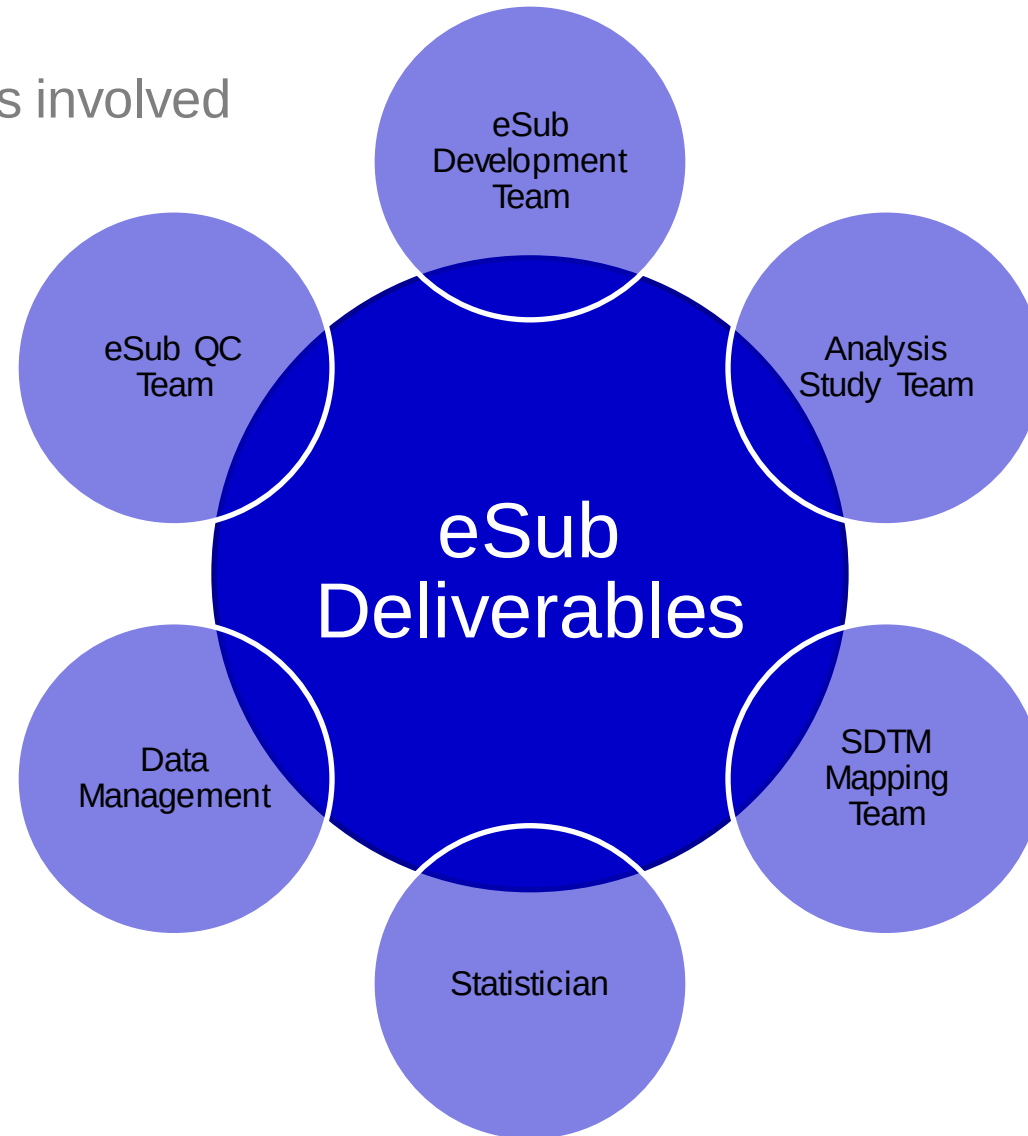
2022 Started off with a BANG!

Delivery Timeline – unprecedented: 15 eSubs, 6 batches of data packages for dispatch



Team Logistics: Roles and Teams

Coordination of many roles involved



Team Logistics: Breakdown of Expectations

Came together and made the impossible POSSIBLE!

Team structure

- Clear assignments, Same people for same components across eSub - efficient to ensure familiarity and quick turnaround
- Good communication, both up and down. Team made aware of all relevant updates in real time - very helpful
- Collaboration is critical to meet aggressive timelines and work in parallel on different submissions

Extensive Planning – Beginning of TLF Development (Proactive Approach)

- eSub Team starts: ADAM/SDTM aCRF, defines, P21 issue management and DRGs
- Study Team starts: Annotated Mock Table Shells, SAS code program files, initial contribution to ADRG
- Alignment of processes across internal and external teams, developed extensive cross checks

Meeting logistics

- Group chats - whole team, DRG team, eSub QC, publishing; helped with focused chats
- Twice daily teams sacrificed off hour work / covered timezones

Tracker

- Timelines for each component, who, what and when – individually tracked
- Source location tab - eSub location, programming environment, Teams
- Helpful to foster team ownership of work

Developed Efficiencies – Lessons Learned

Built the engine while the plane was in flight!



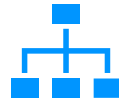
DRG consistencies

- Leveraged existing versions from original eSubs
- Master version w/ placeholders for expected information, e.g., cut-off dates, Incl/Excl appendix or CRF page
- Spreadsheet of agreed standard explanations, DRG section wording



Document flow

- Ensuring *.doc version retained for future
- ### Strict location/logistics
- Restricted only to content reviewers or QC'ers
 - Once component ready for QC, moved to specific folder



Platforms & Systems

- Streamlined
- Alignment of naming convention across systems
- Establishing key systems contacts for immediate troubleshooting



QC Flow

- Preliminary review, catching findings before QC begins
- Started QC for components as they were completed
- Ensured incremental checks were intact, i.e., QC only what changed -- no revisiting other section to get perfection
- New tracker for QCer's to work independently



Partnering with Functions

- Data Management reviewing & commenting directly in P21E
- Standards Mapping team embedded in study team
- Statistics reviewing DRGs

eSub Tracker

eSub Package	Datasets ready for eSub (StudyTeam)	xpt datasets ready for P21 (eSub Team)	P21 Validation (eSub Team)	P21 Explanations	P21 Explanations Review (Study Team)	define.xml (eSub Team)	define.xml Review (Study Team)	Annotated CRF	DRG	DRG Review	DRG QC	eSub QC	eSub Final
Study ID, Description (SDTM: Safety, Immuno etc.);	dd-Jan-2022 (Initials)	dd-Jan-2022 (Initials)	dd-Jan-2022 (Initials)	dd-Jan-2022 (Initials)	dd-Jan-2022 (Initials)	dd-Jan-2022 (Initials)	dd-Jan-2022 (Initials)	dd-Jan-2022 (Initials)	dd-Jan-2022 (Initials)	dd-Jan-2022 (Initials)	dd-Jan-2022 (Initials)	dd-Jan-2022 (Initials)	dd-Jan-2022 (Initials)
Study ID, Description (ADaM: Safety, Immuno etc.);	dd-Jan-2022 (Initials)	dd-Jan-2022 (Initials)	dd-Jan-2022 (Initials)	dd-Jan-2022 (Initials)	dd-Jan-2022 (Initials)	dd-Jan-2022 (Initials)	dd-Jan-2022 (Initials)	dd-Jan-2022 (Initials)	dd-Jan-2022 (Initials)	dd-Jan-2022 (Initials)	dd-Jan-2022 (Initials)	dd-Jan-2022 (Initials)	dd-Jan-2022 (Initials)
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Challenges Met – Technical Issues

Not all smooth sailing

Issues – there were many!

- System failures at key stages causing delays, work standstill, downstream impact on timelines, PANIC
- Limitations of software file security
- Multiple systems and application issues
 - Files vanishing, system glitches, performance, access blocked (due to lapse in external partner logins)
 - Systems and Tools having unplanned downtime for unknown issue

Solutions

- Systems support
 - Identified key contacts to troubleshoot, around the clock
 - Lightspeed Mission Control MS Teams space
 - System Vendors direct line pulled in to solve
- Clear eSub team roles around escalating technical issues
- Improved file transfer system implemented mid-stream allowed for files to be easily moved, deleted
- Pinnacle 21 Enterprise settings
 - P21 tech support recognized the setting causing the issue needs to be better documented (their SMEs didn't easily figure it)

Challenges Met – Data Reviewer's Guides

Not all smooth sailing

Issues – Reviews, changes, edits

- Attempted to manage tightly, yet DRG document management was still challenging
- Versions were copied in both MS Teams & programming env – caused confusion
- PDF rendering done by multiple team members, leading to technical errors
- Many marathon meetings, late night meetings

Solutions

- Created consistency document
 - As challenges arose, immediately added to doc
- Expanded on eSub deliverables platform folder
 - Added Working folder for non-eSub documents
 - Created “Read Me” file
- New workflow for PDF rendering process
- Lots of communication
- Remain flexible and adjust/adapt on the fly

Resource Management

Not all smooth sailing

Collaboration and Planning

Challenge to work across time zones

- Worked around the clock – we just all were working at the same time!
 - Often never logged off before 2 AM everyday
- Fatigue
 - Meetings every 12 hours
 - Half of the team would go to bed and return to work between meetings
 - A day felt more like two days

Unplanned Urgent Requests

- Come in late on a Friday
- Scrambling for resources after hours
- Disruption of personal plans
 - In transit to relocate – called from car, hotel, etc.
- Delivered on time!

Managing Resource Unavailability

- National holidays -- Planned to allow team time off, as best as we could
- Key team member on planned leave (e.g., maternity leave), emergencies, fatigue, falling ill

Many “known unknowns”

- eSub strategy and timelines changed rapidly, i.e., hour to hour.
- Team pulled into multiple meetings within single day, for multiple days.
- Team moving forward without clear expectations, yet knowing eSubs needed



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Questions





Thank You

