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THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION



Advancing Global Regulatory Submissions through Next Generation Submission (NGS)

A Collaborative Implementation Case Study

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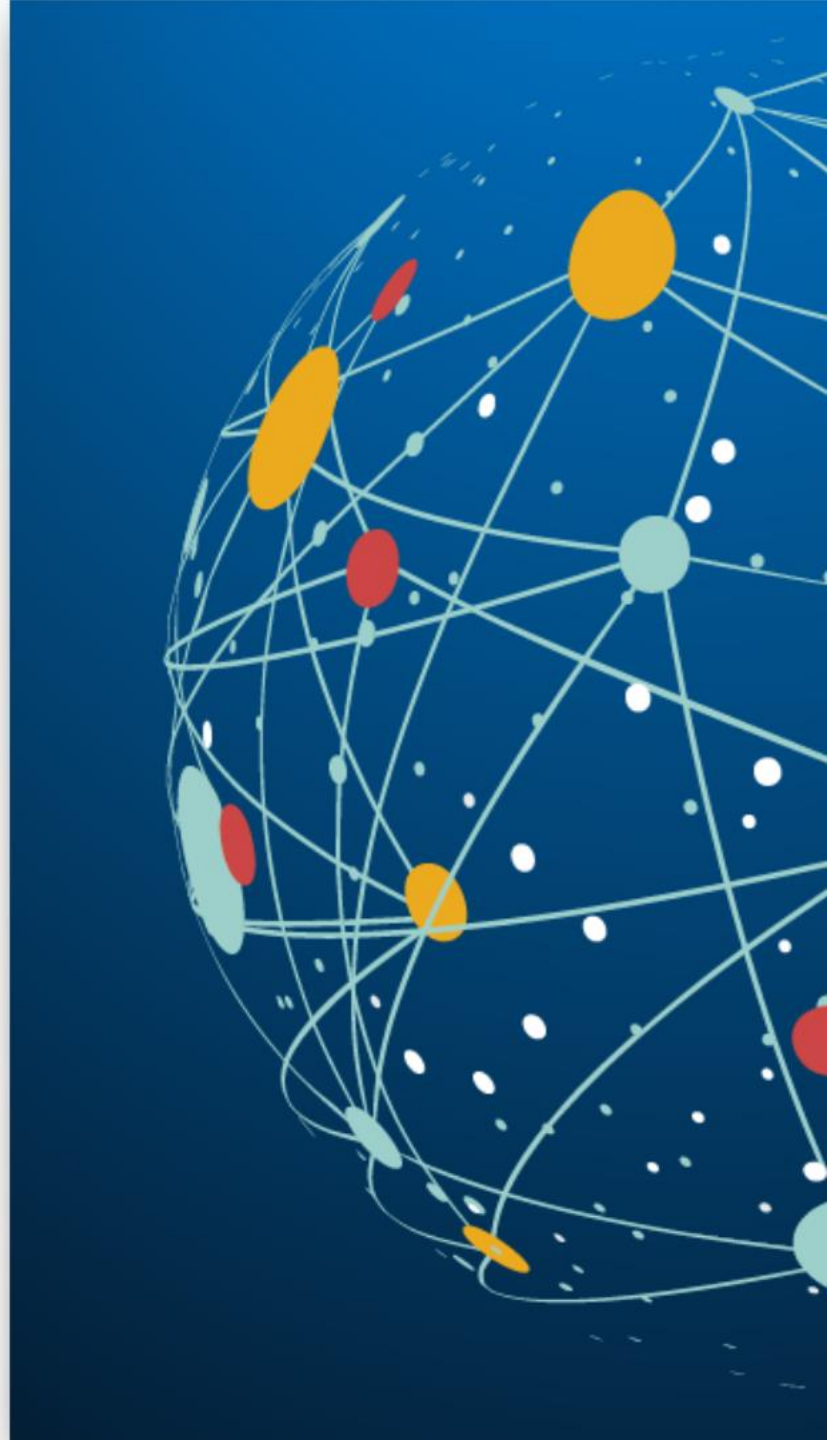
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AGENDA

1. Abstract
2. Background & Introduction
3. NGS Levers
4. NGS Strategy
5. Case Study
6. Results and Conclusions



Abstract

The adoption of Next Generation Submission (NGS) levers is transforming global regulatory submission preparation through standardized, automation-driven processes and accelerated timelines. This collaborative CRO–sponsor case study focuses on pre-DBL planning, a dress rehearsal approach, and post-DBL strategies.

Key levers include multi-regional CDISC alignment, an early-access shadow team for restricted unblinded PK/ADA data, CSR reduction planning, and automation for in-text tables and safety narratives. Structured governance and iterative approaches addressed cross-functional coordination, intercurrent event handling, third-party vendor data transfer, and regional variability.

The case demonstrates a more efficient, scalable and future-ready submission process with improved consistency, reduced timelines and strengthened regulatory compliance.



Background & Introduction

Background:

With the rapid advancement of technology especially AI implementation, the R&D of innovative therapies has entered a new era of accelerated growth. To more effectively improve human health and address critical unmet medical needs, pharmaceutical organizations are motivated to expedite the analysis and reporting of clinical trial data, streamline regulatory submissions to agencies for review and approval.

Objective:

By adopting Next Generation Submission (NGS) levers, we aim to transform our preparation of global regulatory submissions, work more efficiently and sustainably to deliver accelerated yet high-quality global regulatory submissions through standardized, automation-driven, more efficient processes.

Case Study:

A collaborative submission acceleration of NGS implementation between a CRO and a global sponsor, focusing on pre-DBL planning, Dress Rehearsal approach, and post-DBL strategies.



Transforming our submissions process

To deliver medicines to patients faster than we do today, we will make changes across:



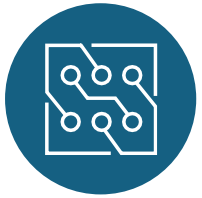
People

Changing how we work and adjusting our approaches and role profiles



Process

Streamlining to reduce manual effort and maximise efficiency



Technology

Harnessing technology and automation with an integrated end-to-end platform



Governance

Clear and consistent decision-making for certainty and accountability

Key Levers to Achieve an Accelerated NGS Submission Timeline

LEVER 1: Strong planning and communication

- Regular A/R (Analysis/Reporting), data review and optimization meetings; ad hoc meetings; Teams communication
- NGS checklist covering scope, review, data cleaning, resources, timing and ownership
- Prompt communication of needs and expectations
- Key decisions and comment responses documented in a tracker

LEVER 2: Align key study documents across functions

- Engage medical writing early for SAP and mock-shell review
- Align algorithms and clinical review sheets across functions
- Stabilize SAP and TFL mock shells early, such as after Dry Run 1
- Finalize HLR (High-Level Results)/CSR and subgroup output lists before DBL



Key Levers to Achieve an Accelerated NGS Submission Timeline

LEVER 3: Monitor data cleaning and TPV data to targets

- Establish a cleaning and delivery plan for EDC and all TPV (third-party vendor) data
- Monitor and review imaging, central laboratory and PK/ADA data
- Use dummy data in dry runs to prepare programming code early
- Create a separate shadow team with restricted early access to unblinded PK/PD/ADA data
- Identify real-data issues early, support cleaning and update code before DBL



Key Levers to Achieve an Accelerated NGS Submission Timeline

LEVER 4: HLR dry run and dress rehearsal close to DBL

- Add HLR Dry Run 2.5 to support fast, accurate delivery after DBL
- Run a dress rehearsal immediately before DBL so functions practice the reduced timeline
- Use the rehearsal to uncover data transfer, review and delivery issues early

LEVER 5: Agree the post-DBL delivery strategy and timing

- Track HLR, CSR, ISS/ISE, in-text tables, subgroup packages, safety narratives, BIMO and eCRT
- Monitor all milestones and ownership against the agreed plan



Alignment with Major Global Regulatory Submission Requirements

Requirement	FDA	PMDA (Japan)	EMA (Europe)
CDISC Standards	**Mandatory,** SDTM & ADaM Data Required	**Mandatory,** SDTM & ADaM Data Required	**Not Mandatory,** but Yes for clinical study data pilot / proof-of-concept
Compliance/Validation Check	Pinnacle 21 is commonly used following FDA TCG(Technical Conformance Guide) and validation criteria/business rules, Error/Warning Focus, serious conformance issues must be resolved or reasonable explanation provided	Pinnacle 21 is used, Reject Rules apply, rejections and other serious violations must be fixed	Yes for Pilot studies
Unit Standards	SI unit / Conventional unit (CU can be used on some occasions)	Mandatory SI Units	SI unit
Define-XML with ARM	Define-XML and reviewer's guide are required for SDTM/ADaM datasets, but Analysis Results Meta(ARM) is optional depending on study design	Define-XML and reviewer's guide are required for SDTM/ADaM datasets, but Analysis Results Meta(ARM) is expected for primary efficacy and safety endpoints	Define-XML is required for Pilot studies, while ARM is optional
BIMO Package	Required to faciliate site inpsection	Not Required	Not Required
Regional Subgroup Analysis	a more general subgroup/region analysis may be needed	Japan subgroup analysis is required	a more general subgroup/region analysis may be needed

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Strategy and Implementation of Shadow Team

1. Set up a separate unblinded shadow team with early access to restricted unblinded PK/PD/ADA data
2. Set up an exclusive working area for shadow team
3. Set up restricted TEAMs channels with TPV vendors respectively to ensure effective and prompt communication
4. Review and re-run SDTM/ADaM datasets and related TLFs using the unblinded PK/PD/ADA data and report all the issues identified to the vendor and AZ unblinded team so that the issues can be addressed as early as possible before DBL. The issues may include duplicate records, missing values, outliers, inconsistency between Data Transfer Specification(DTS) and TPV data, etc., which don't exist in the dummy data
5. Update the SAS programs based on the unblinded data to make sure the programming code covers all of the real situations

Automation Enhanced In-text Tables and Safety Narrative

1. In-Text Tables

- Developed utility macro to efficiently convert post-text tables to in-text tables per medical writer's requirement, including title/footnote styling, subtitles, griding, contents styling, etc.
- Developed utility tool to handle footnote formatting, indentation, styling, etc.
- Conduct in-text tables dry-run and address comments, ensure to deliver in-text tables quickly after DBL

2. Safety Narrative

- Developed macros for patient selection criteria, dynamically adjust narrative contents and layout based on each selected patient's data presentation.
- Highly modulized sections for domain table/listing section and clinical narrative/sentence section, with a master macro to integrate all sections together for each patient's narrative file

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Case Study: A Collaboration between AstraZeneca and ClinChoice

Case Study Background:

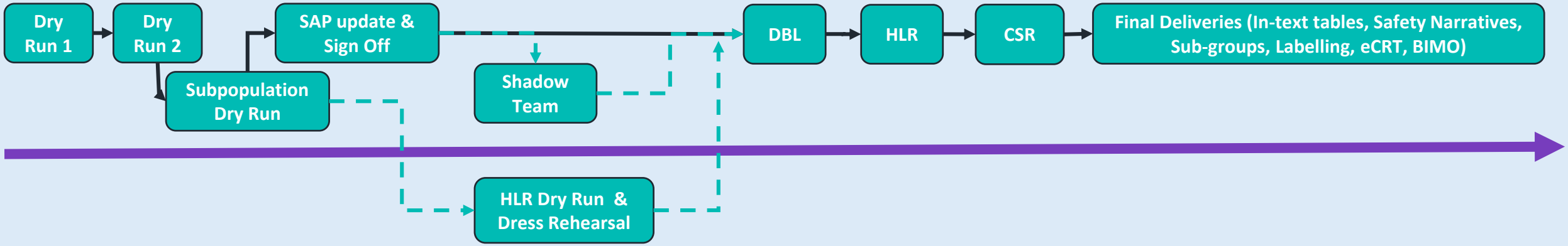
A pivotal Phase III study to evaluate the efficacy and safety of investigational product in patients with a respiratory disease. AstraZeneca is the sponsor, ClinChoice is the A/R(Analysis & Reporting) vendor for Statistics and Programming of this study.

NGS submission target for ClinChoice is to deliver:

- HLR (High-Level Results) within 3 working days post DBL
- CSR package within 5 working days post HLR delivery
  - HLR scope (15-20 TFLs, HLR related SDTM/ADaM datasets)
  - Other items to be delivered following CSR (In-text Tables, Safety Narratives, Sub-populations, Labelling requests, eCRT, BIMO, etc.)

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Case Study: A Collaboration between AstraZeneca and ClinChoice



Time
Standard Timeline
NGS Timeline

❖ **NGS Levers Used:**

- Strong planning and Communication plan
- Shadow team
- HLR dry run
- Dress Rehearsal
- Automation
- Multi-regional Submission Alignment
- Post-DBL delivery strategy plan in place

Case Study - Wins

1. AstraZeneca and ClinChoice teams collaborated very well and worked as one unified team
2. Strong planning to utilize NGS levers, checklist, pre-DBL and post-DBL delivery strategy
3. Efficient communication, problem-solving focused
4. Utilizing shadow team which helped identify issues ahead of DBL and helped DM team to clean data to ensure data quality
5. Utilizing HLR dry-run 2.5 and dress rehearsal dry-run, which enable cross-functional teams to practice NGS timeline before DBL to ensure timely turn-around of HLR/CSR deliverables after DBL with high quality

Case Study - Walls

1. Overlapping activities and timeline
2. Incremental deliverable scope expansion
3. Discrepancy between TPV data and DTS (Data Transfer Spec)
4. Additional data check needed to ensure data quality
5. Complex Multiple-Imputation algorithm

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Case Study – Wisdoms

1. Highly recommend scheduling dress rehearsal close to DBL to practice final timelines
2. Cross-functional alignment on algorithm, especially for implementation of clinical review sheet for Inter-Current Event (ICE) and Prohibited Medication Review Sheet
3. For studies with >3 years duration, plan feasible and efficient timelines for extra review of SAP and mock shells
4. Utilizing decision and comment tracker to ensure accurate algorithm/approach implementation
5. Utilizing data review meeting and make sure old data issues are resolved

Case Study Results: NGS vs Previous Standard Timeline

Delivery	NGS: Delivery Days Post Receipt of DBL Data	Previous Standard: Delivery Days Post Receipt of DBL Data
Receipt of DBL data	0	0
HLR (SDTM/ADaM datasets and outputs)	2	3
Unvalidated CSR ADaM datasets	5	optional
CSR (full SDTM/ADaM datasets, TLFs)	8	18
In-text tables	9	20
Safety Narratives	11	23
Sub-populations (Japan, China, Asia, etc.)	16	28
eCRT package (Define-XML and Reviewers' Guide)	18	33
BIMO package	21	36

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Results and Conclusions

- With implementation of NGS levers including shadow team, extra HLR dry-run, dress rehearsal, the timeline to deliver HLR and CSR packages were significantly reduced. The A/R team was able to deliver HLR (High-Level Results) 2 days after receiving DBL data, which is 1 day earlier than the planned timeline
- HLR results and CSR packages are delivered with high-quality while meeting the accelerated NGS timeline
- With strong planning and efficient utilization of automation tools, In-text tables and sub-populations packages were delivered earlier which greatly helped medical writer team and global submission team for the final submission

The above results demonstrate improved submission process, consistent quality, reduced timelines, and enhanced regulatory compliance.

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Questions and Comments?

Thank you!

