

Managing Deliverables in Oncology Basket Trial

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Agenda

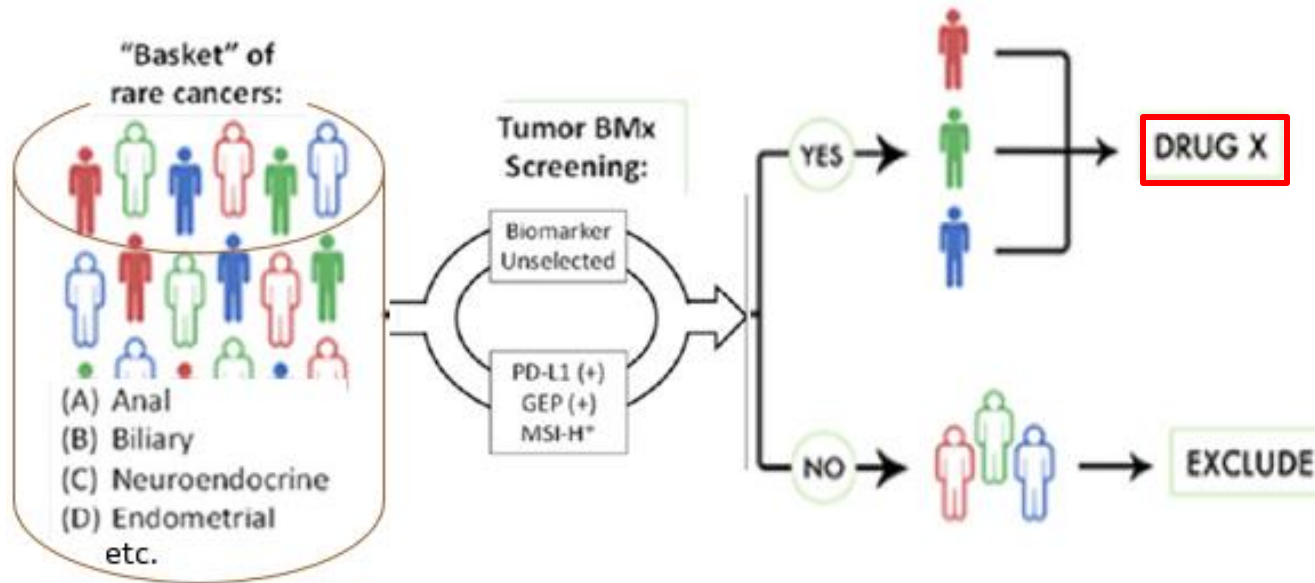
- Background
- Project Management and Planning
 - Resource
 - Study Folder Structure
 - ADaM Specification/Datasets
- Communication and Documentation
- Automation
 - Standardization/Automation of Study Report Generation
- Conclusion
- Contact Information
- Acknowledgement



Background

Basket trial

- a novel approach to expedited clinical development of innovative oncology products



Multiple cancer populations

Same treatment

Features

- Frequent interim analysis (IA) - objectives
 - early evaluation and prediction of endpoints
 - conference presentations
 - journal publications
 - agency requests
 - submissions to regulatory agencies
- Scope of deliverables per IA
 - 100s to 1,000s reports
- Submission activities
 - in-parallel, multiple indications, multiple agencies
 - RTOR, ORBIS, ODAC, etc.

Solutions

- Project management and planning
- Communication and documentation
- Automation

Project Management and Planning (PMP)

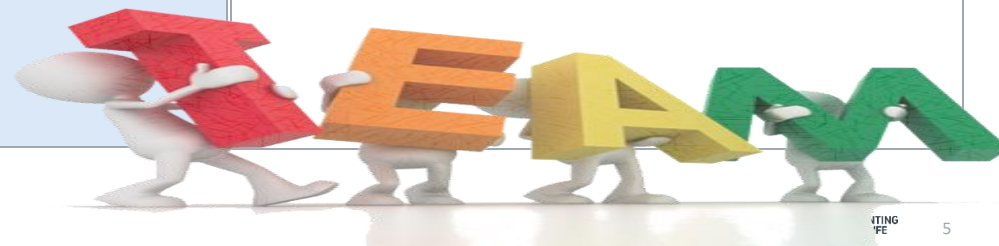
- Agile and compliant project management is essential for any new circumstances encountered in a basket trial



PMP - Resource

- To manage the dynamic deliverables for a basket trial
 - Require a **flexible Statistical Programming (SP) project team size** with both dedicated and flexible resources

Dedicated Resource		Flexible Resource
Lead	Team Members	Team Member
○ Working with management and multi-functional areas: resource planning ○ Technical approach design/development ○ Process management ○ Team mentoring ○ Oversight: all IAs/submission deliverables	○ Protocol template/macro program development/validation ○ Key A&R deliverables for each IA ○ Some submission packages	○ Additional unplanned support ✓ >1 submissions/IA ✓ Oncologic Drugs Advisory Committee (ODAC) meeting ✓ ...

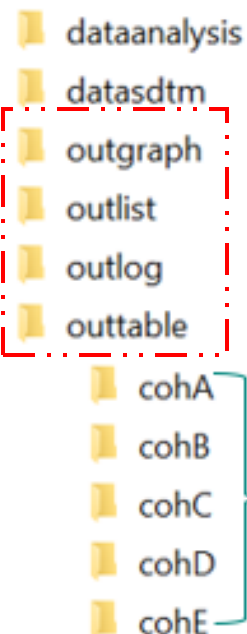


PMP – Study Folder Structure

- Folder hierarchy & naming conventions to properly organize and support **broad deliverables** and provide **traceability** to the context of each folder

Per cohort

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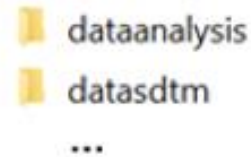
Output

- easy to locate
- automate generation

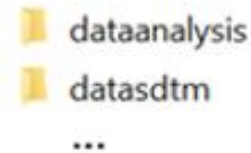
Subfolders for each cohort under “output” folders in the main IA folder

Per submission

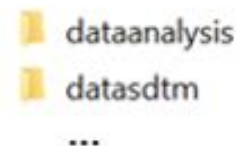
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Submission documents

- organized
- related IA

Submission folders

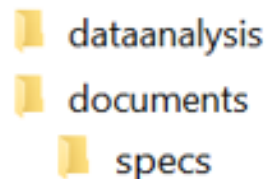
- **parallel to the IA_x folder**
- naming convention traceable to the corresponding IA

PMP – ADaM Specification/Datasets

- Data collection and analysis requirements, and course of therapy may vary among participants of different cancers
- To ensure consistency and quick turnaround across IAs and submissions

Main IA/All cohorts

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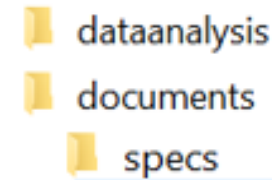
Required ADaM datasets/variables for all participants

ADaM-Dataset-Spec...999.xlsm

- Different variable derivation rules among cancer types
- Information for exploratory analysis

Per submission/cohort

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Unique scenario for the related cancer type/population submission

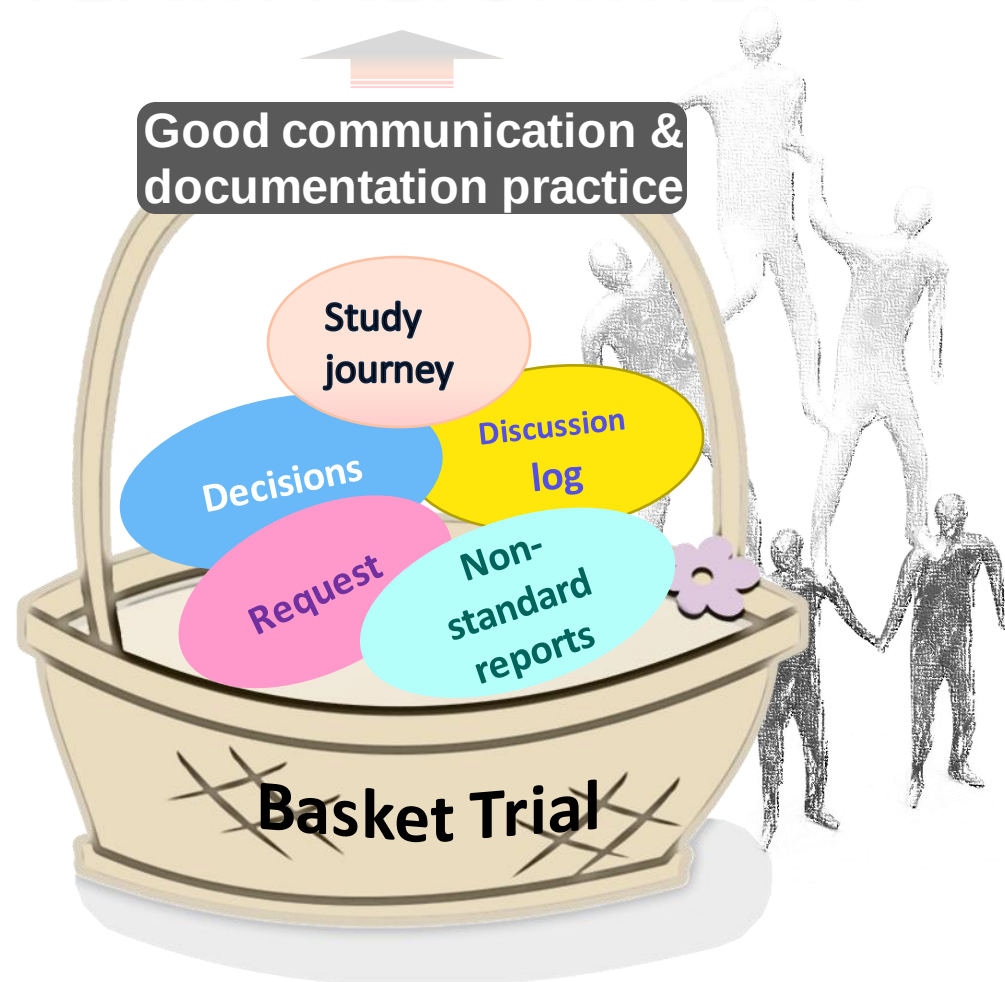
ADaM-Dataset-Spec...999_cohA.xlsm

- Data for limited participant
- Prior therapy unique to certain cancer type, e.g., Platinum for SCLC

Help streamline an ADaM data development and validation process with compliance, accuracy, and efficiency for a basket trial with multiple IAs and submissions

Communication and Documentation

TEAM ALIGNMENT



X

Excel tool - easy forum to search information

Meeting agenda/minutes

- weekly meeting
- updates on
 - ✓ project decision
 - ✓ Timeline
 - ✓ related standards/guidelines
- follow-up on assignments
- issue discussion
- upcoming tasks
- resource

Assignments

- track the A&R requests (not fit in the standards tracking tools)
- show the status/location/progress
- show team's workload
- help address new requests using the previous similar work recorded



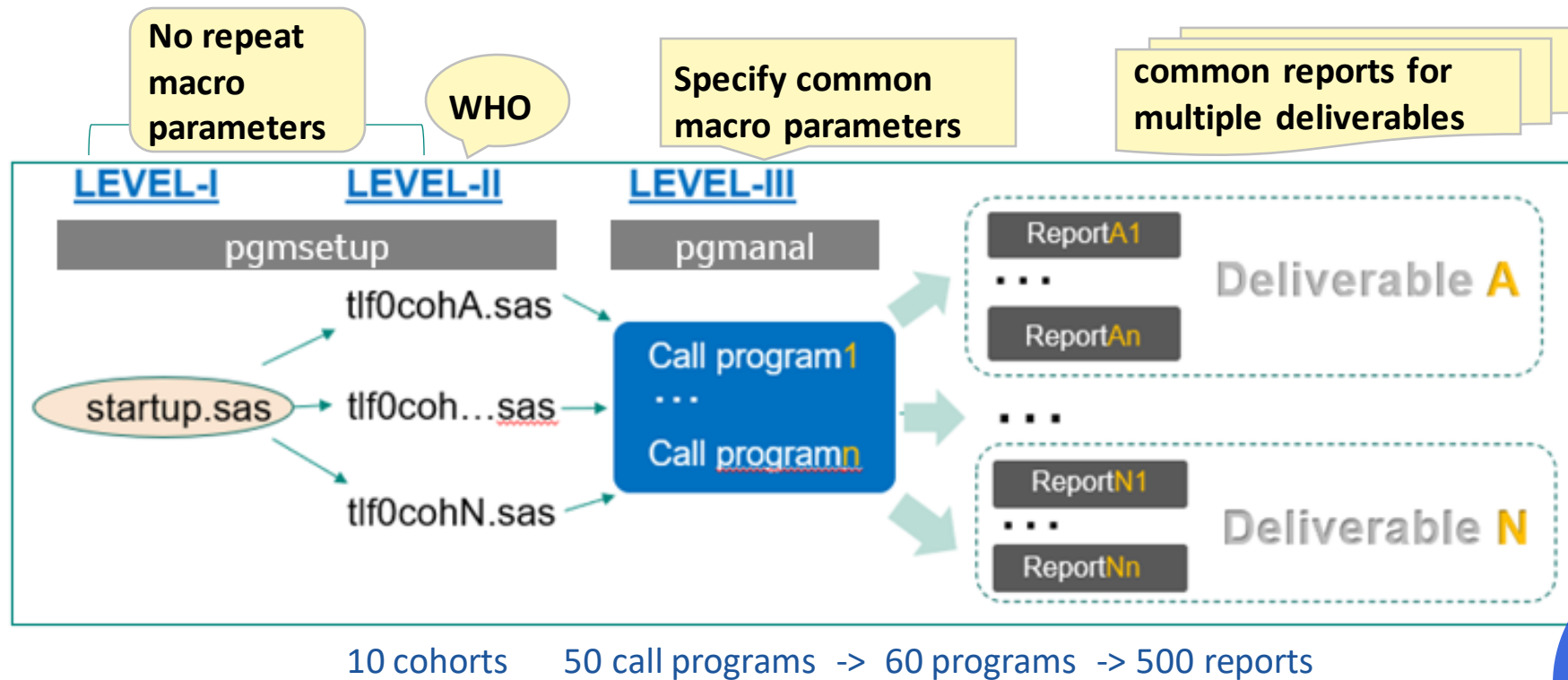
Instant message group: urgent resource need

- for team to sign up the support quickly

-
- A decorative graphic on the right side of the page featuring several interlocking gears. The gears are colored in shades of blue, orange, and grey. Inside the gears are various icons: a document with a checklist, a magnifying glass over a document, a bar chart with an upward arrow, and a circular flow diagram. The gears are arranged in a cluster, with some overlapping. A blue and white diagonal graphic element is visible on the far left edge of the page.

Automation - Standardization/Automation of Study Report Generation

- Process: report generation with macro call program templates (**Level-III**) and **Level-II** programs



Ensure quality

Conclusion

BASKET TRIAL

- designed to study the safety and efficacy of an investigational product among patient populations with different tumor types and/or biomarkers
- aiming at early identification of efficacious treatment for patients in need
- the implementation: frequent IAs for publications and/or multiple accelerated submissions across study cohorts in the same IA and/or across IAs simultaneously
- significant challenges to A&R resource, process, and techniques

SOLUTIONS

- To adapt an agile, flexible approach under the general guideline and SOP to improve efficiency and productivity
- Careful and innovative planning and implementation of resource, project management, and programming techniques

IMPACT

- Some essential elements (project management, technical approaches) developed are transferable to traditional oncology trials



Contact Information

Your comments and questions are valued and encouraged. Contact the authors at:

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*Thank
You*