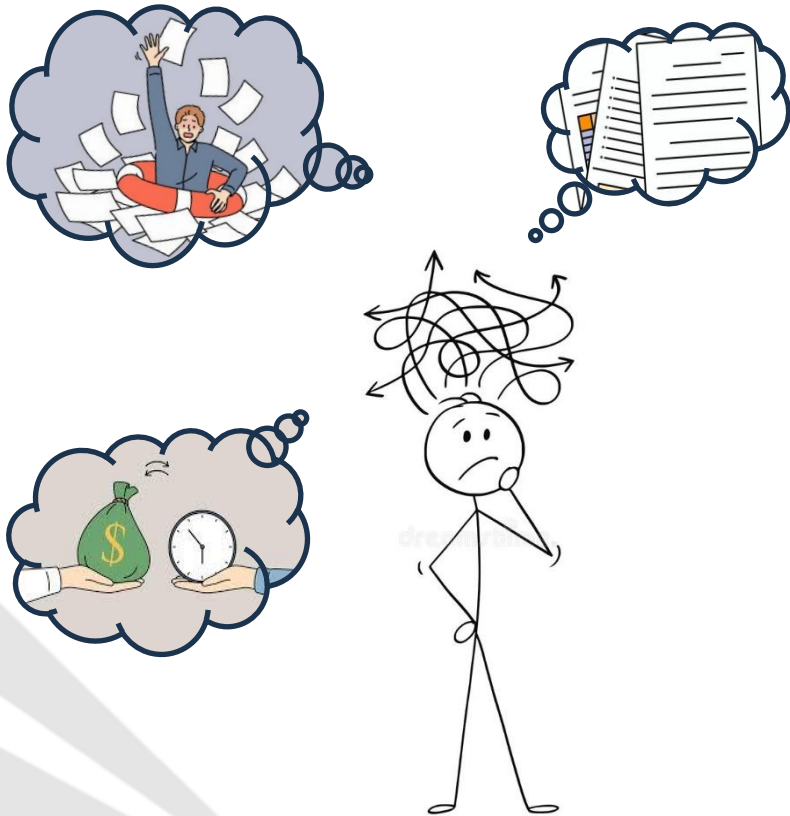# Sponsor Documented Procedures for IITs

14 Nov 2025

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Innovation Office & Clinical Trials Branch
Health Products Regulation Group
Health Sciences Authority, Singapore

Outline

- Documented Procedures to be Maintained by A Sponsor For IITs

- Change Control and Training Records

- Tips and Reminders

- Summary

Q: What are the things that come to mind when you think about sponsor's documented procedures?

Live Results

System-level Documented Procedures to be maintained by a Sponsor for IITs

Trial start-up

- Clinical Trial Agreements
- Budgeting
- Risk-based Quality Management
- Initial application to IRB
- Initial application to HSA
- Data collection and handling
- Using Computerised Systems
- Trial Master Files

Trial Conduct

- Investigator Site Monitoring
- Continuing Review / Trial Status Reports
- Study / Substantial amendments
- Deviations, Non-compliances, Serious Breaches & Urgent Safety Measures
- Safety Assessment and Safety Reporting

Trial Completion

- Trial Completion / Termination

Essential Records

C.3   **Essentiality of Trial Records**

C.3.1   The assessment of whether a record is essential and has to be retained should take into account the criteria below. Such assessment, whilst important, is not required to be documented. A structured content list for storage repository(ies) may be used to prospectively identify essential records. An essential record:

Essential Records Table

If these trial records are produced, they are considered essential and should be retained (see sections C3.1 and C3.2).

Note: An asterisk (*) identifies those essential records that should generally be in place prior to the start of the trial (see section C2.5).
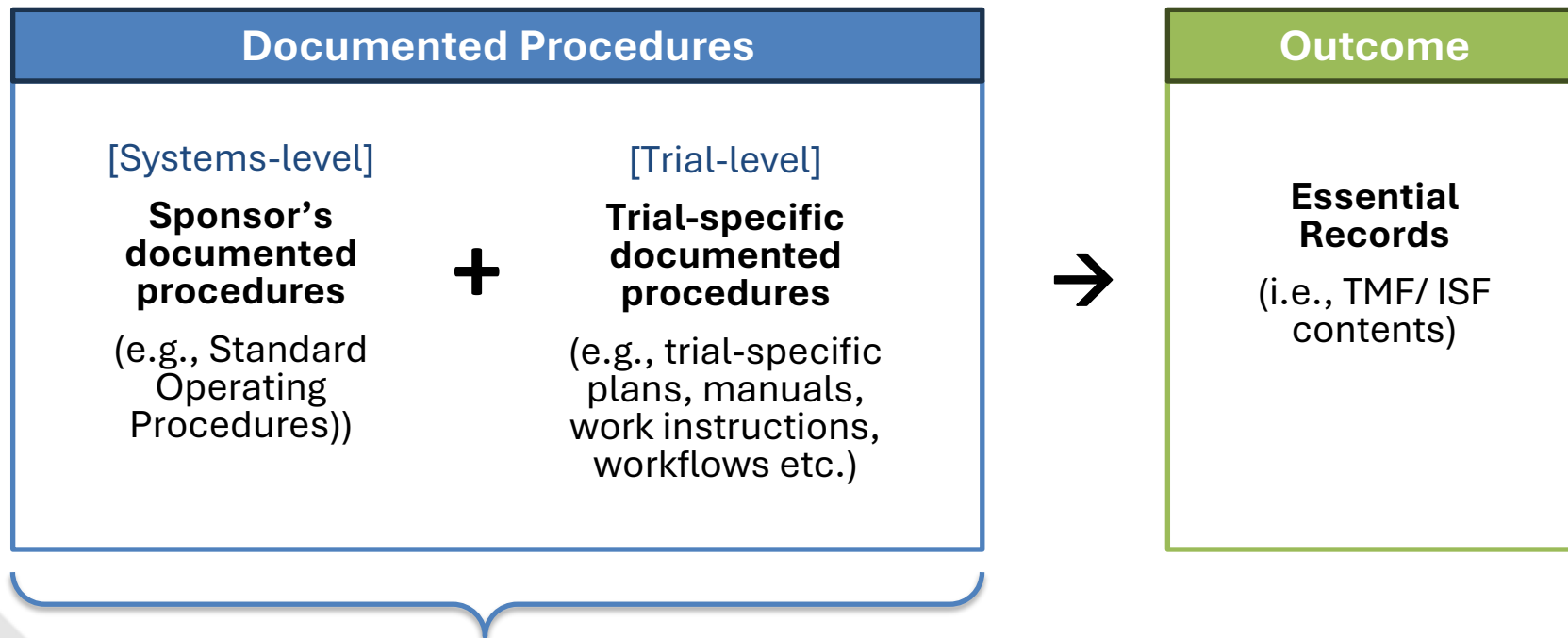
Investigator's Brochure or basic product information brochure (e.g., summary of product characteristics, package leaflet or labelling)*
Signed protocol* and subsequent amendments during the trial
Dated, documented approval/favourable opinion of IRB/IEC of information provided to the IRB/IEC*
IRB/IEC composition*

Q: How can we use Appendix C (Essential Records) as a guide to determine which sponsor-documented procedures are required?

Documented Procedures		Outcome
[Systems-level] **Sponsor's documented procedures** (e.g., Standard Operating Procedures))	**+** **[Trial-level]** **Trial-specific documented procedures** (e.g., trial-specific plans, manuals, work instructions, workflows etc.)	**Essential Records** (i.e., TMF/ ISF contents)

→

Procedures should be **complementary,** not **contradictory!**

Fried Egg Analogy

Documented Procedures

[Systems-level]
KITCHEN SOP

+

[Protocol-level]
COOKING MANUAL

SOP 1. How and when to procure kitchen equipment?

SOP 2. Where and how to store and maintain kitchen equipment?

SOP 3. How and when to procure ingredients?

SOP 4. Where and how to store ingredients ?

SOP 5. Qualifications of the Cook

SOP 6. Selection process of Cooks

How to Fry an Egg

You need:

- 1 large egg
- 1 teaspoon olive oil
- Pinch of sea salt and black pepper
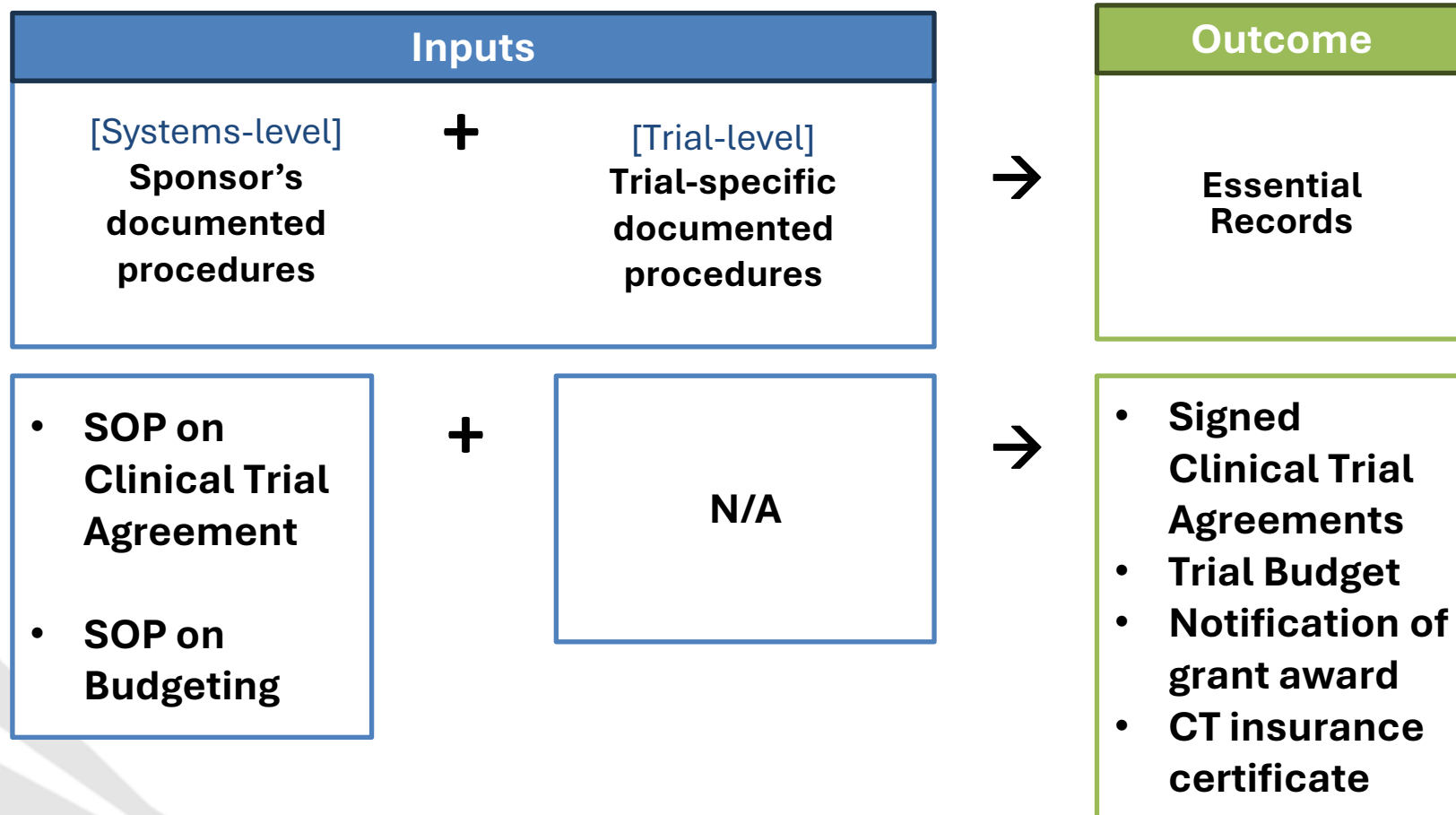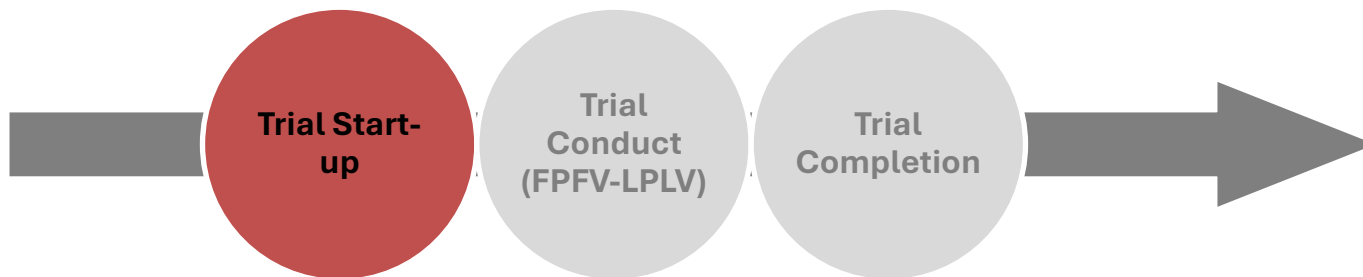- Cast iron skillet, stove

Chef's Instructions:

1. Crack the egg into a small bowl.
2. Heat olive oil over medium heat in a pan.
3. Carefully pour in the egg.
4. Cover and cook for 2-3 minutes.
5. Transfer to a plate and serve.
6. Reinstate the kitchen workspace.

→

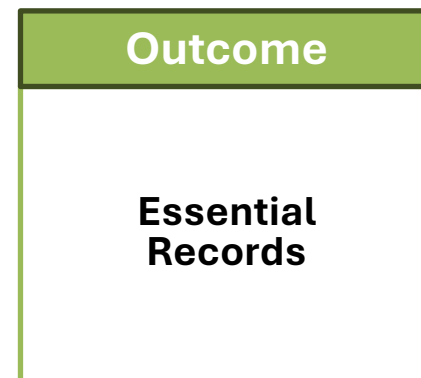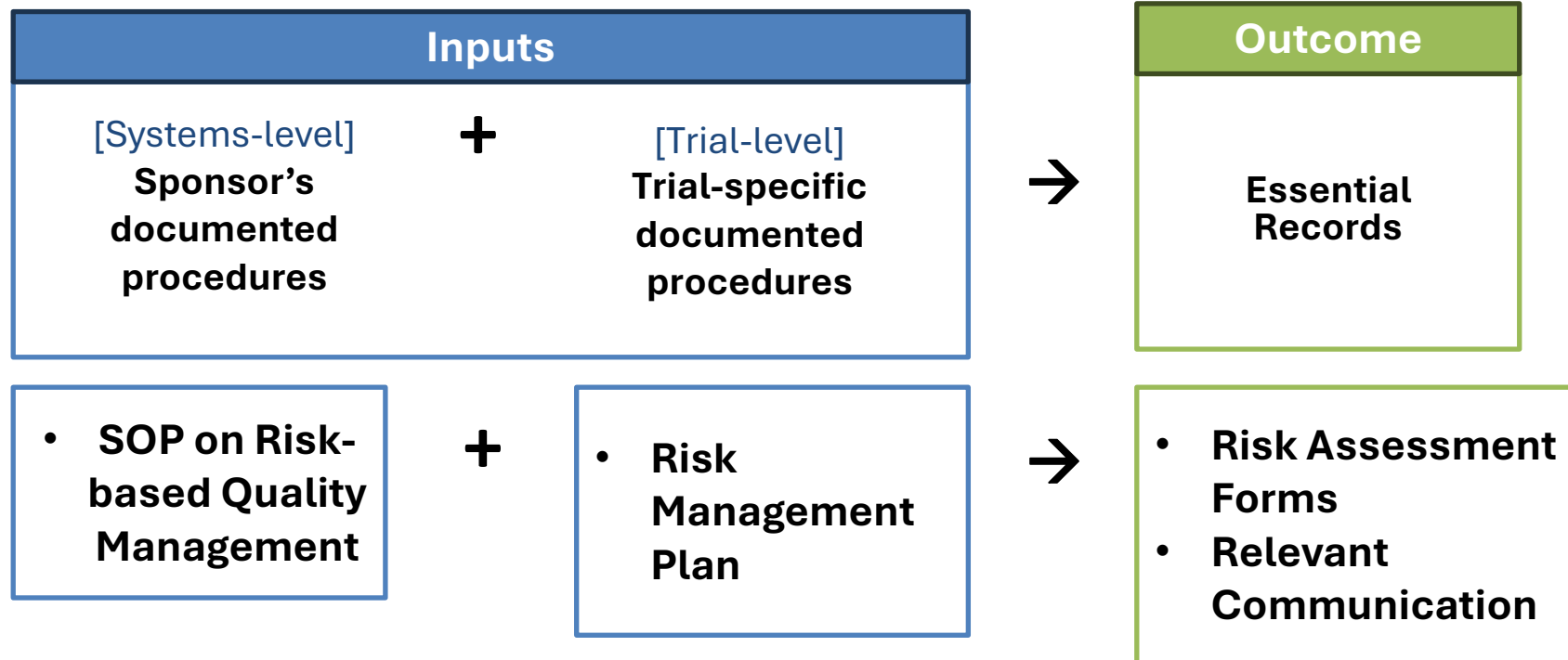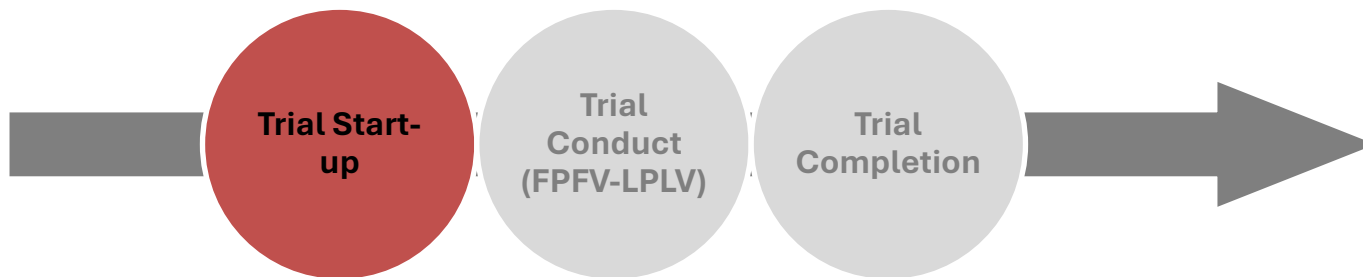## Outcome

ESSENTIAL "RECORD"

Trial Start-up | Trial Conduct (FPFV-LPLV) | Trial Completion

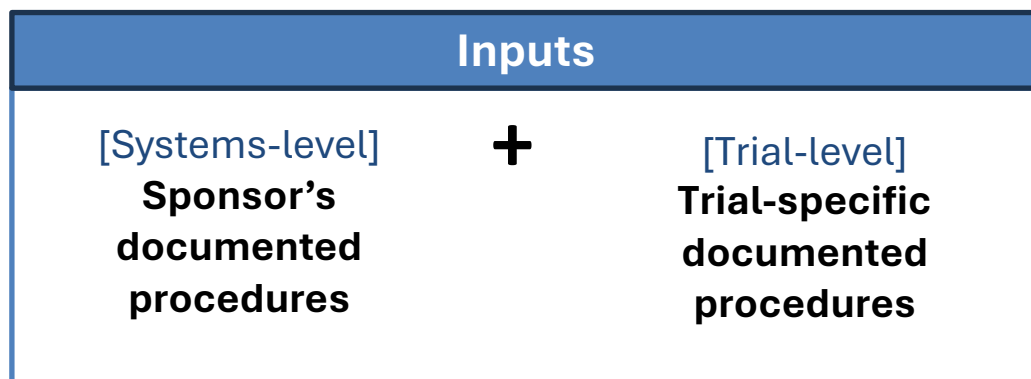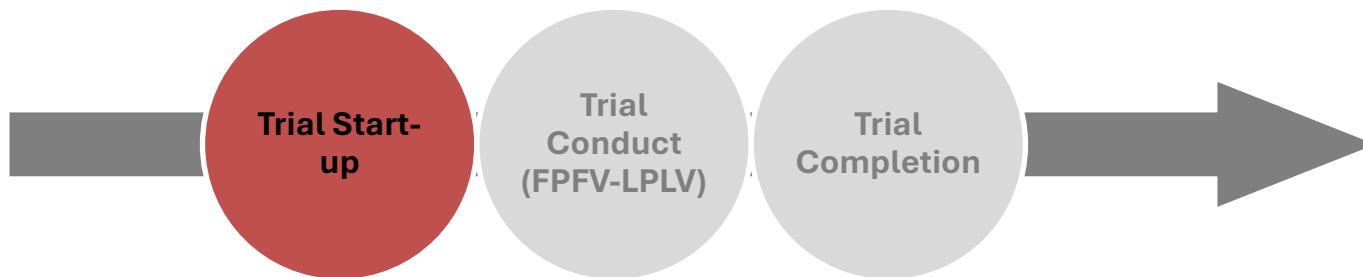| Inputs			Outcome
[Systems-level] **Sponsor's documented procedures**	**+** [Trial-level] **Trial-specific documented procedures**	→	**Essential Records**
• **SOP on Clinical Trial Agreement** • **SOP on Budgeting**	**+** **N/A**	→	• **Signed Clinical Trial Agreements** • **Trial Budget** • **Notification of grant award** • **CT insurance certificate**

Note: The examples of documented procedures provided in this presentation are intended as a guide and are non-exhaustive.
Sponsors should assess and determine the appropriate documented procedures based on the nature, scope, and complexity of their clinical trial activities.
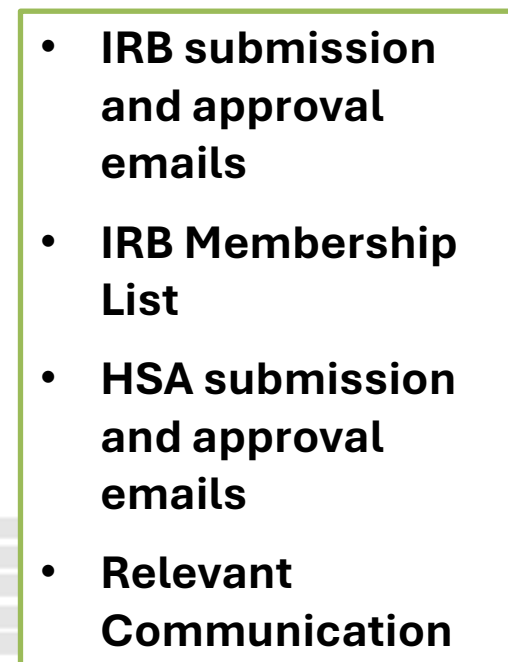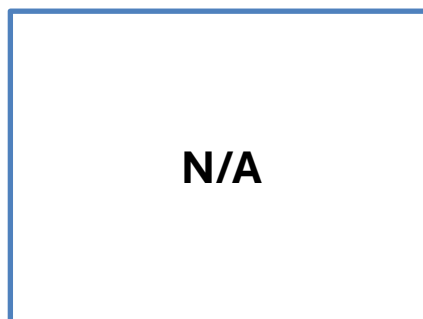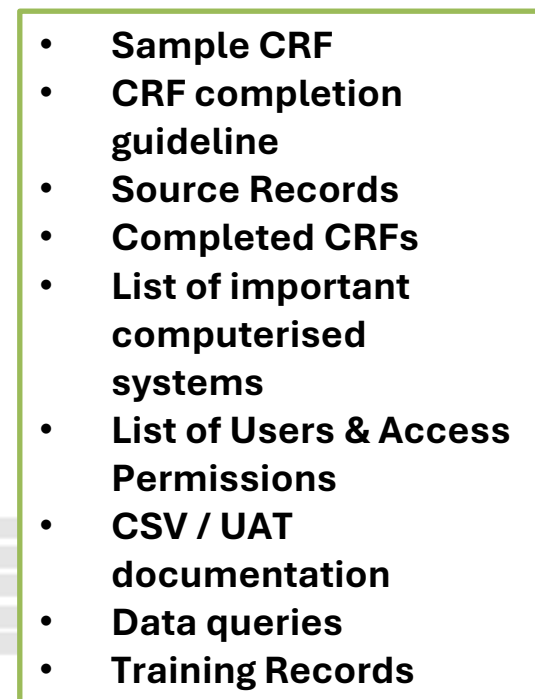
Trial Start-up | Trial Conduct (FPFV-LPLV) | Trial Completion

Inputs

[Systems-level]
Sponsor's documented procedures

+

[Trial-level]
Trial-specific documented procedures

→

Outcome

Essential Records

- **SOP on Risk-based Quality Management**

+

- **Risk Management Plan**

→

- **Risk Assessment Forms**
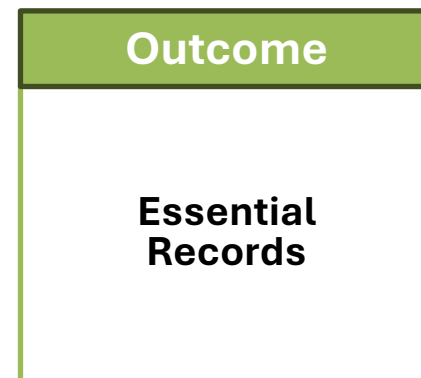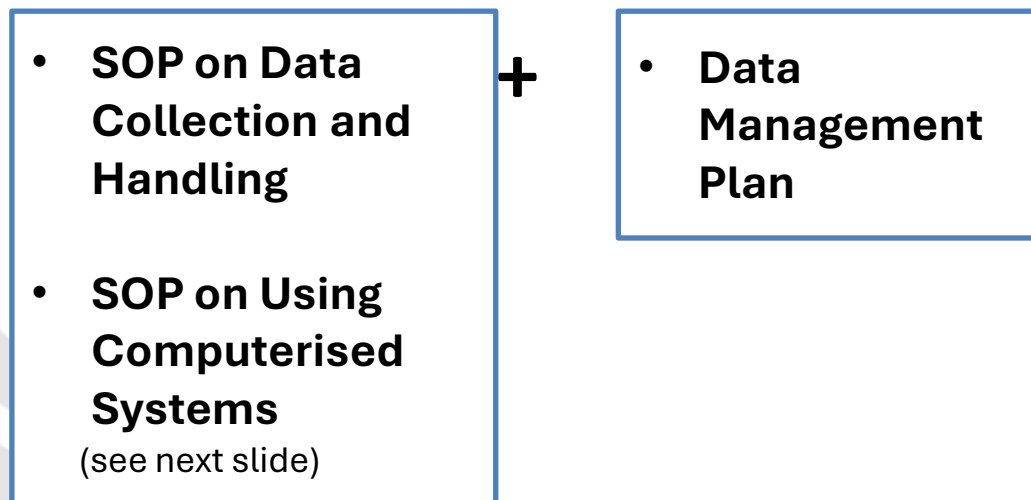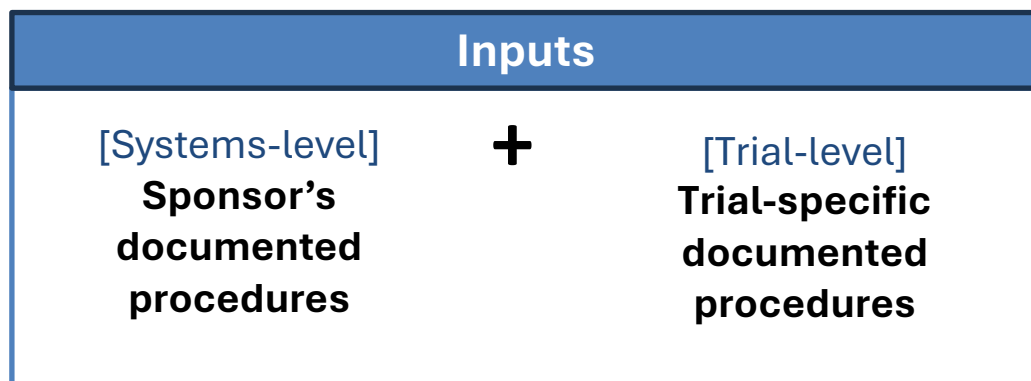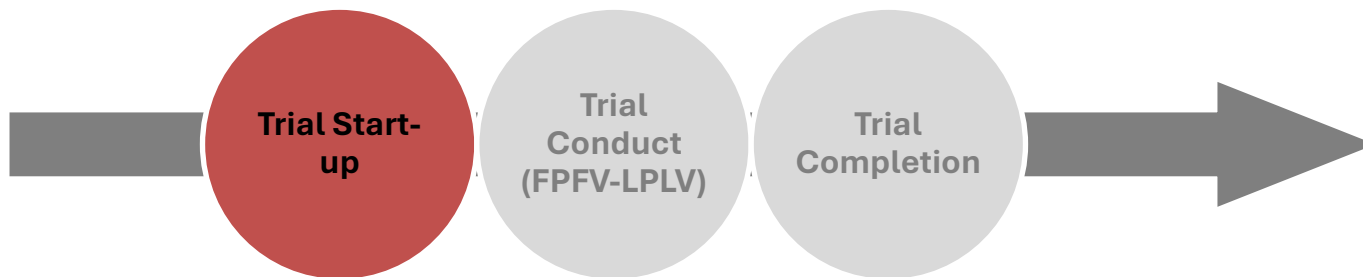- **Relevant Communication**

Note: The examples of documented procedures provided in this presentation are intended as a guide and are non-exhaustive.
Sponsors should assess and determine the appropriate documented procedures based on the nature, scope, and complexity of their clinical trial activities.

Trial Start-up → Trial Conduct (FPFV-LPLV) → Trial Completion

| Inputs		Outcome
[Systems-level] **Sponsor's documented procedures** + [Trial-level] **Trial-specific documented procedures**	→	**Essential Records**
• **SOP on Institutional Review Board (IRB) and Regulatory Authority (RA) Submissions** + **N/A**	→	• **IRB submission and approval emails** • **IRB Membership List** • **HSA submission and approval emails** • **Relevant Communication**

Note: The examples of documented procedures provided in this presentation are intended as a guide and are non-exhaustive.
Sponsors should assess and determine the appropriate documented procedures based on the nature, scope, and complexity of their clinical trial activities.

Trial Start-up → Trial Conduct (FPFV-LPLV) → Trial Completion

Inputs

[Systems-level]
Sponsor's documented procedures

+

[Trial-level]
Trial-specific documented procedures

→

Outcome

Essential Records

- **SOP on Data Collection and Handling**

- **SOP on Using Computerised Systems**
  (see next slide)

+

- **Data Management Plan**

→

- **Sample CRF**
- **CRF completion guideline**
- **Source Records**
- **Completed CRFs**
- **List of important computerised systems**
- **List of Users & Access Permissions**
- **CSV / UAT documentation**
- **Data queries**
- **Training Records**

Note: The examples of documented procedures provided in this presentation are intended as a guide and are non-exhaustive.
Sponsors should assess and determine the appropriate documented procedures based on the nature, scope, and complexity of their clinical trial activities.

Documented Procedures for Data Collection and Handling

Data lifecycle elements
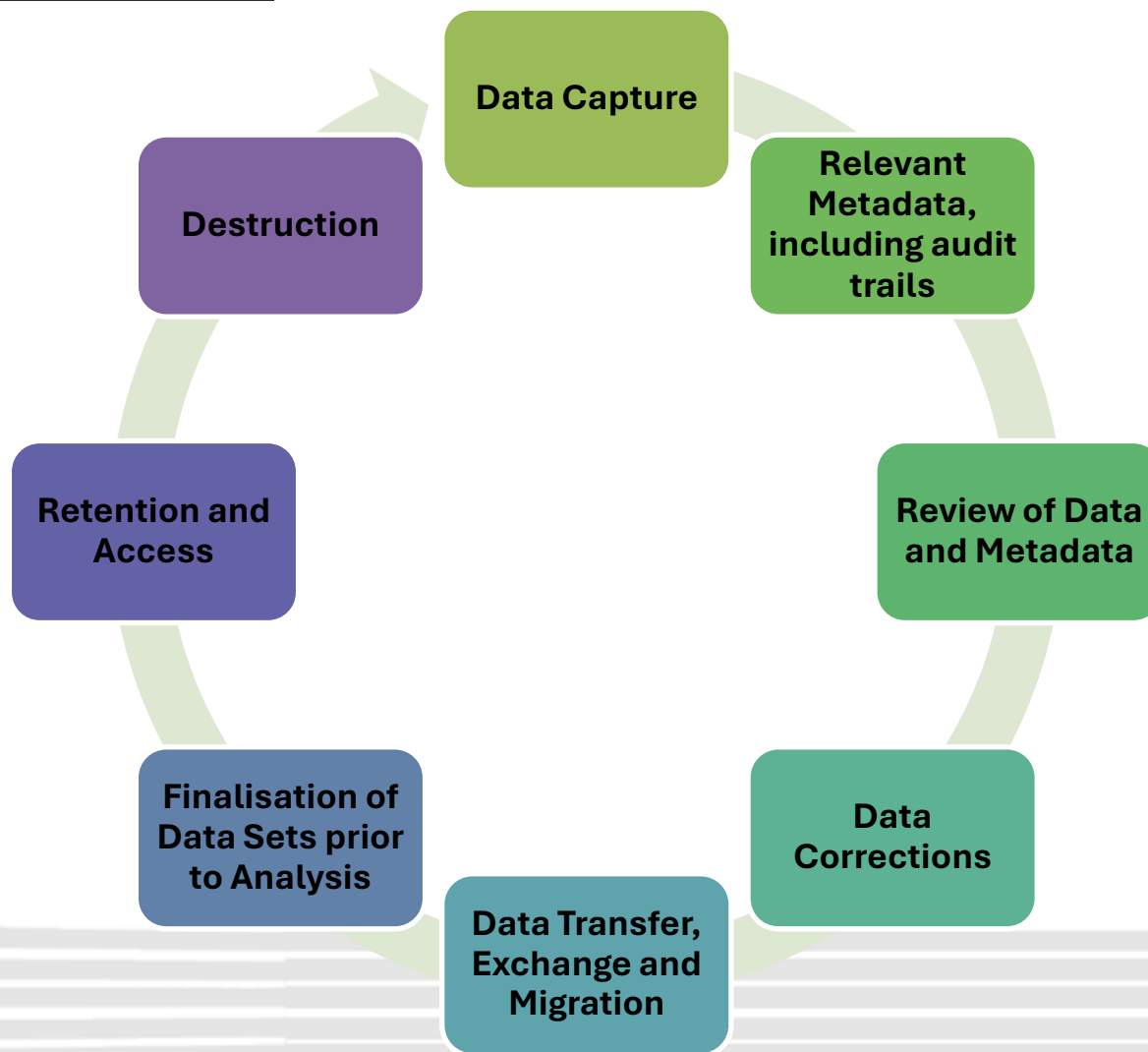
Documented Procedures for Computerised Systems
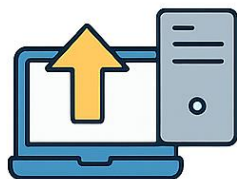
System Installation and Setup

System Validation and Testing
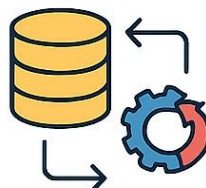
User Access and Training

Data Collection and Handling

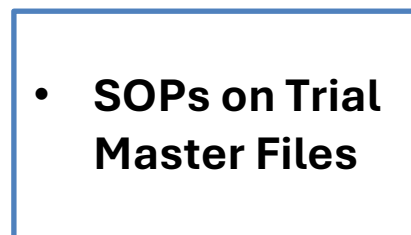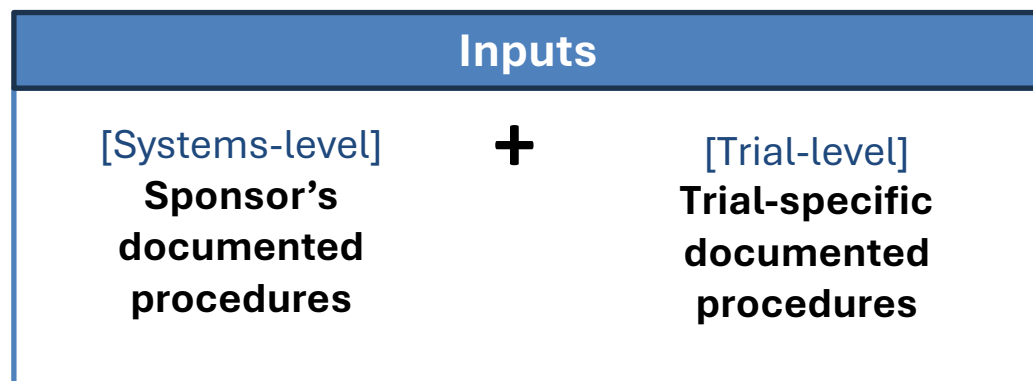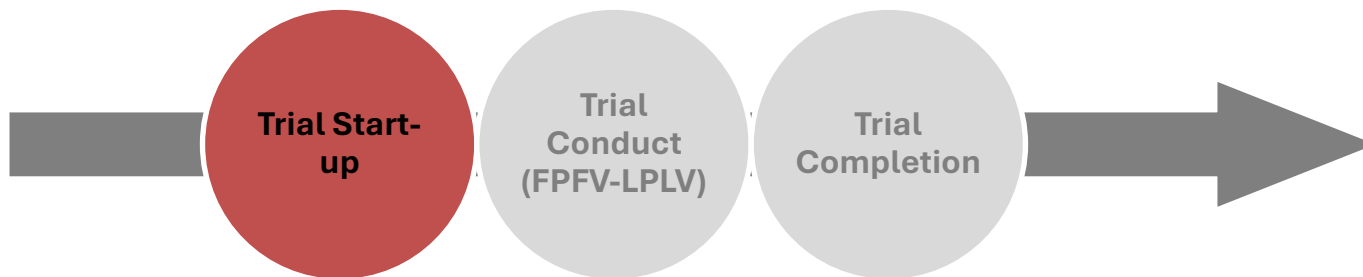Data Integrity and Audit Trails

System Maintenance

Backup and Recovery

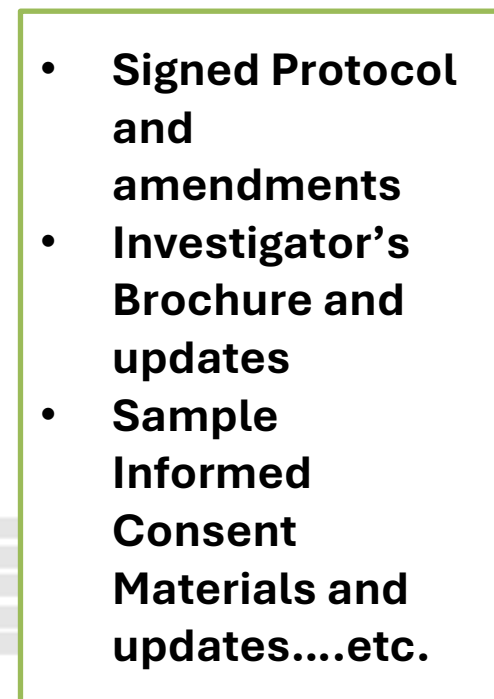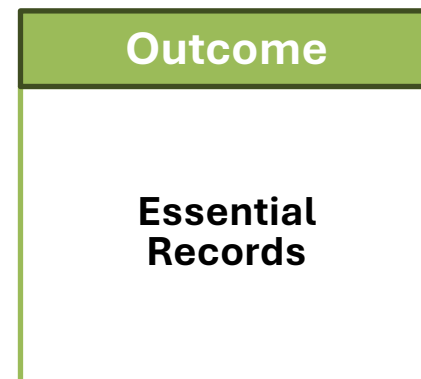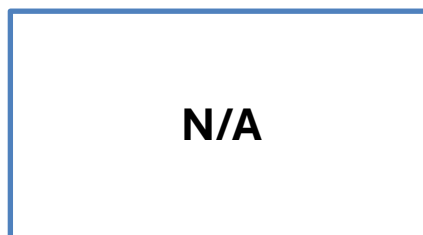Change Control

Decommissioning

Trial Start-up → Trial Conduct (FPFV-LPLV) → Trial Completion

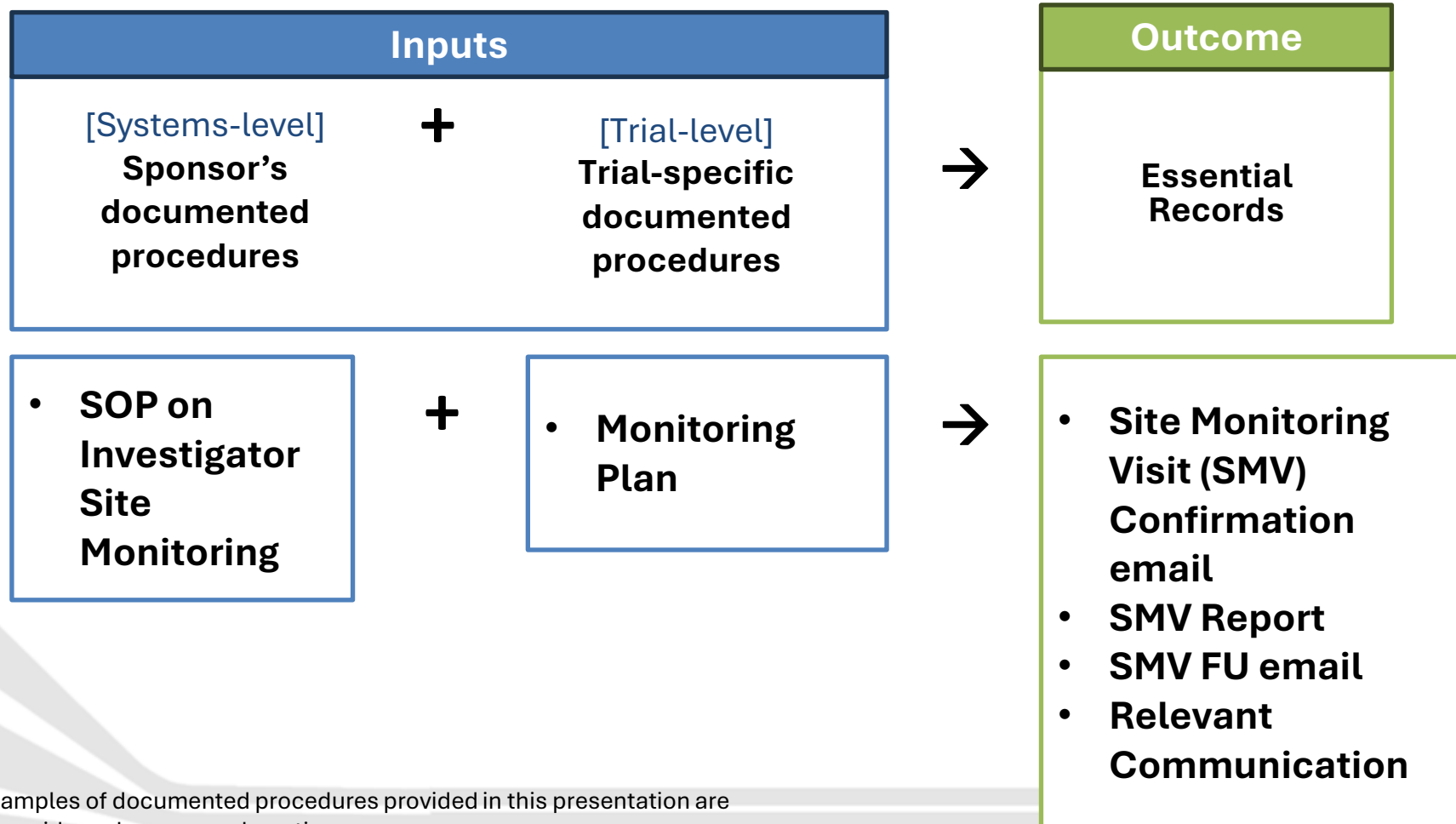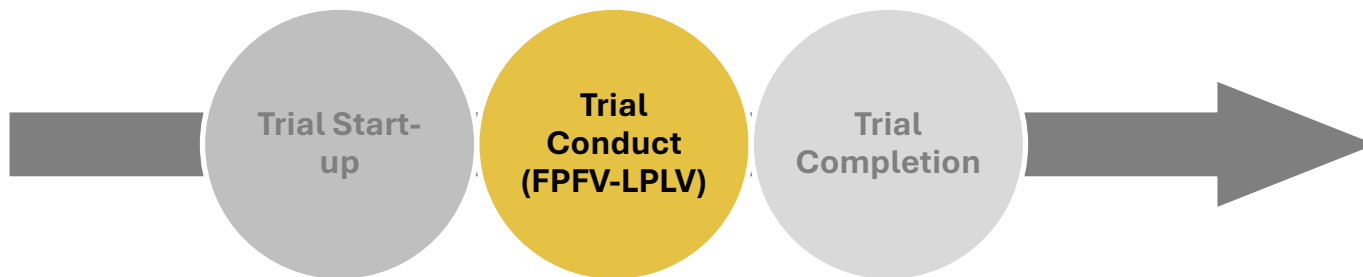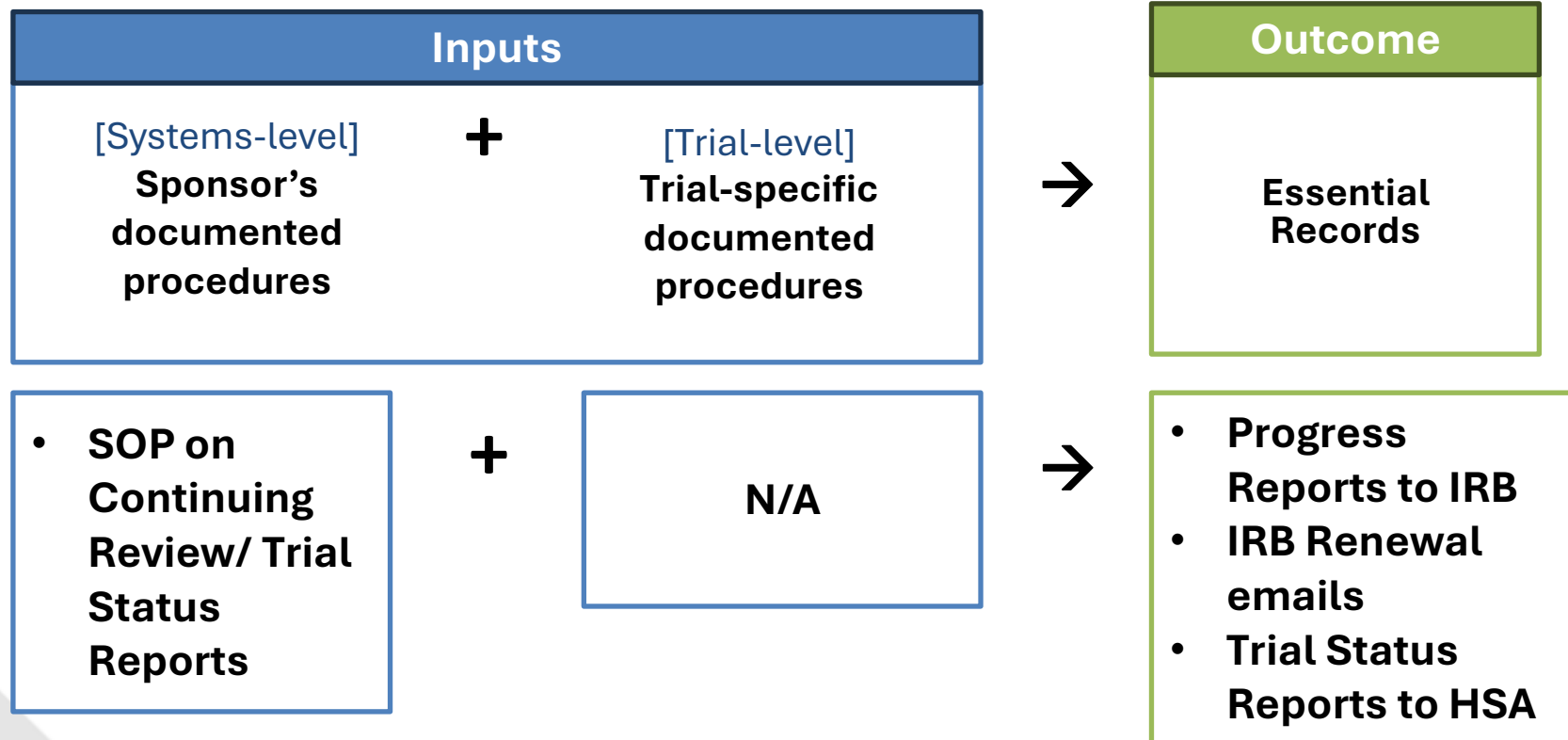| Inputs			Outcome
[Systems-level] **Sponsor's documented procedures**	**+**	[Trial-level] **Trial-specific documented procedures**	→ **Essential Records**
• **SOPs on Trial Master Files**	**+**	**N/A**	→ • **Signed Protocol and amendments** • **Investigator's Brochure and updates** • **Sample Informed Consent Materials and updates....etc.**

Note: The examples of documented procedures provided in this presentation are intended as a guide and are non-exhaustive.
Sponsors should assess and determine the appropriate documented procedures based on the nature, scope, and complexity of their clinical trial activities.

Trial Start-up → **Trial Conduct (FPFV-LPLV)** → **Trial Completion** →

Inputs

[Systems-level]
Sponsor's documented procedures

+

[Trial-level]
Trial-specific documented procedures

→

Outcome

Essential Records

- **SOP on Investigator Site Monitoring**

+

- **Monitoring Plan**

→

- **Site Monitoring Visit (SMV) Confirmation email**
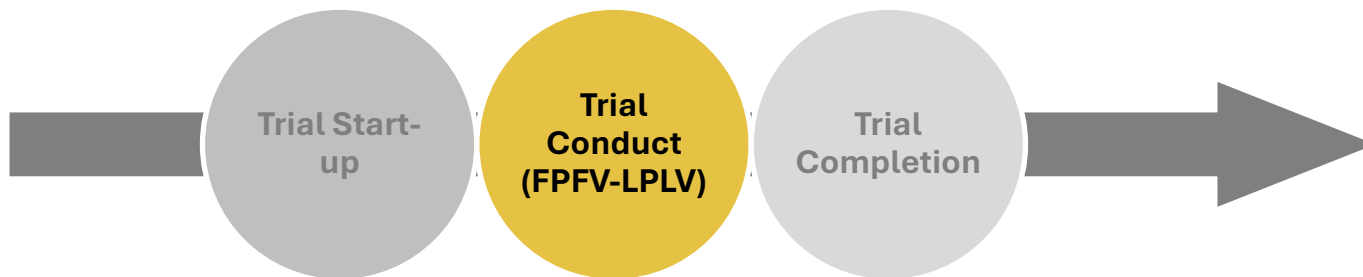- **SMV Report**
- **SMV FU email**
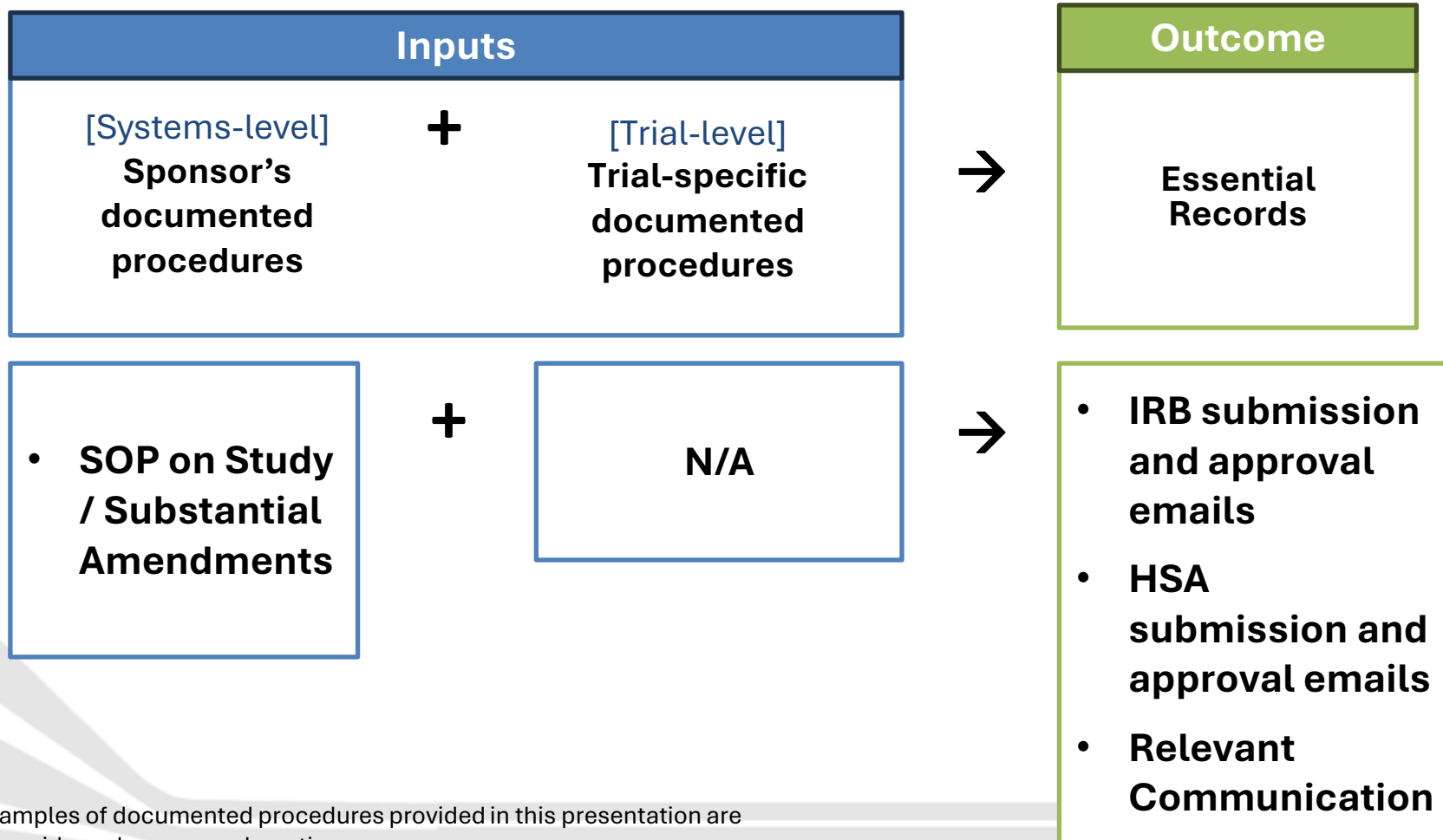- **Relevant Communication**

Note: The examples of documented procedures provided in this presentation are intended as a guide and are non-exhaustive.
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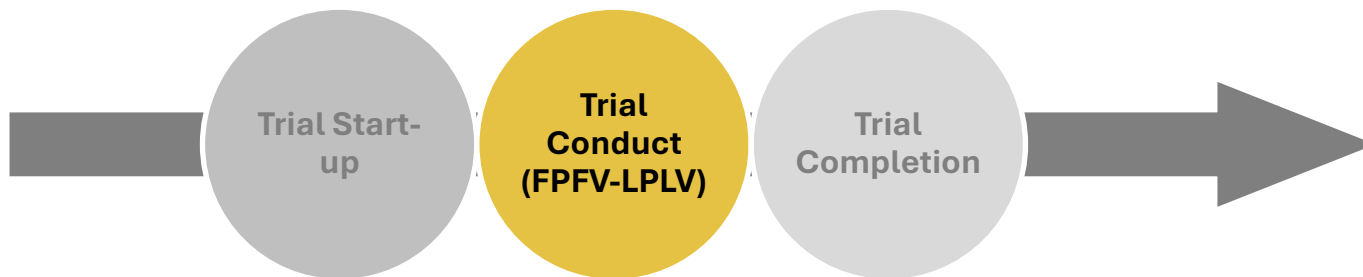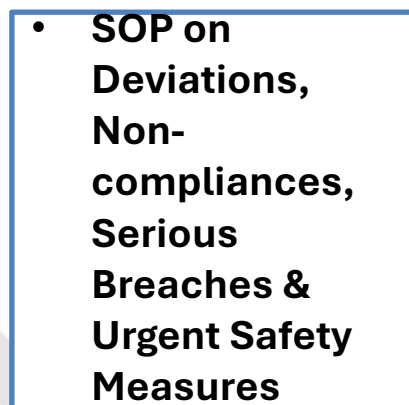
Note: The examples of documented procedures provided in this presentation are intended as a guide and are non-exhaustive.
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Trial Start-up | Trial Conduct (FPFV-LPLV) | Trial Completion

Inputs

[Systems-level] **Sponsor's documented procedures**

+

[Trial-level] **Trial-specific documented procedures**

→

Outcome

Essential Records

- **SOP on Study / Substantial Amendments**

+

N/A

→

- **IRB submission and approval emails**
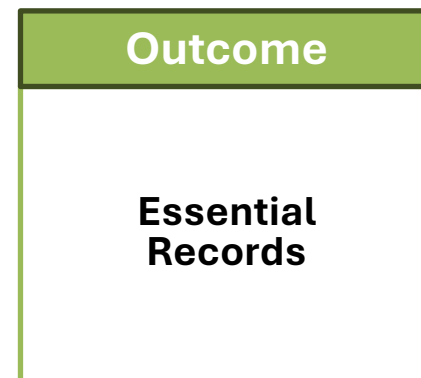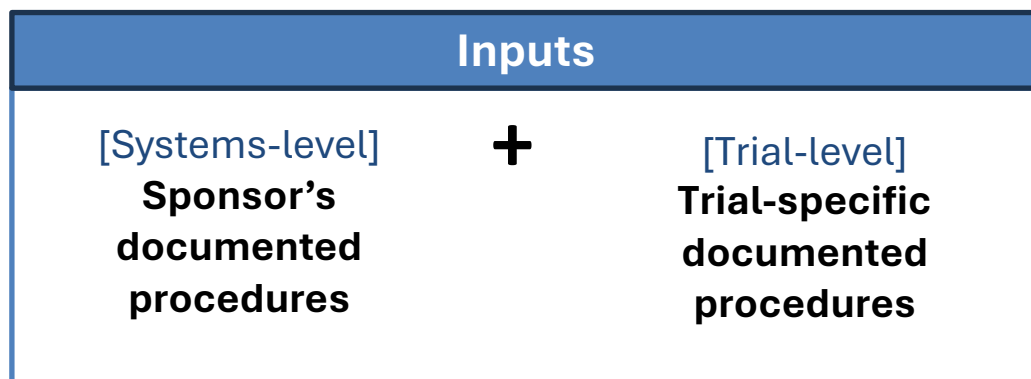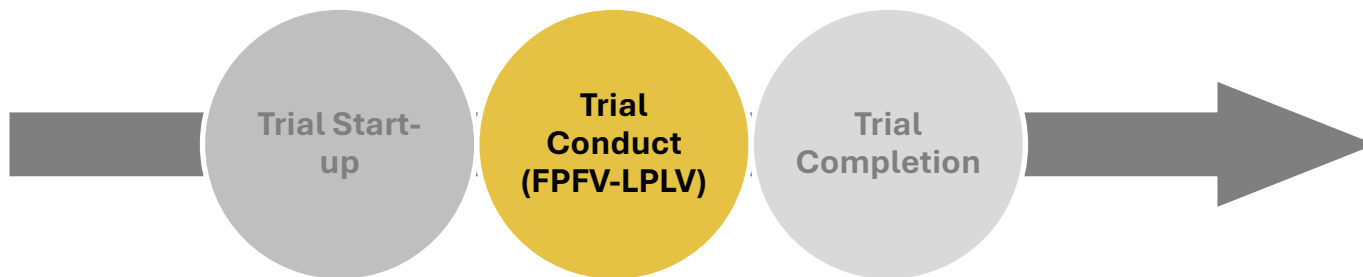- **HSA submission and approval emails**
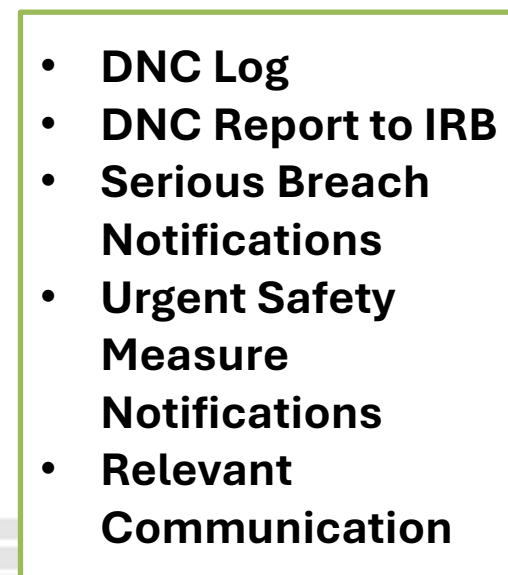- **Relevant Communication**

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Sponsors should assess and determine the appropriate documented procedures based on the nature, scope, and complexity of their clinical trial activities.

Trial Start-up → **Trial Conduct (FPFV-LPLV)** → Trial Completion →

Inputs		Outcome
[Systems-level] **Sponsor's documented procedures** **+** **[Trial-level]** **Trial-specific documented procedures**	→	**Essential Records**

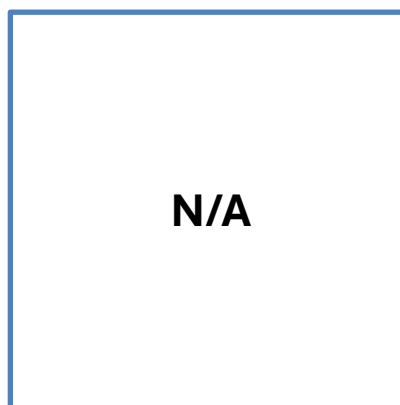|		
• **SOP on Deviations, Non-compliances, Serious Breaches & Urgent Safety Measures** **+** **N/A**	→	• **DNC Log** • **DNC Report to IRB** • **Serious Breach Notifications** • **Urgent Safety Measure Notifications** • **Relevant Communication**

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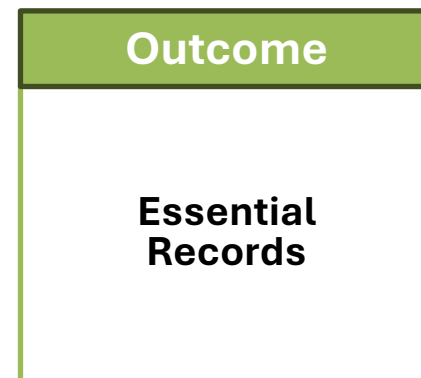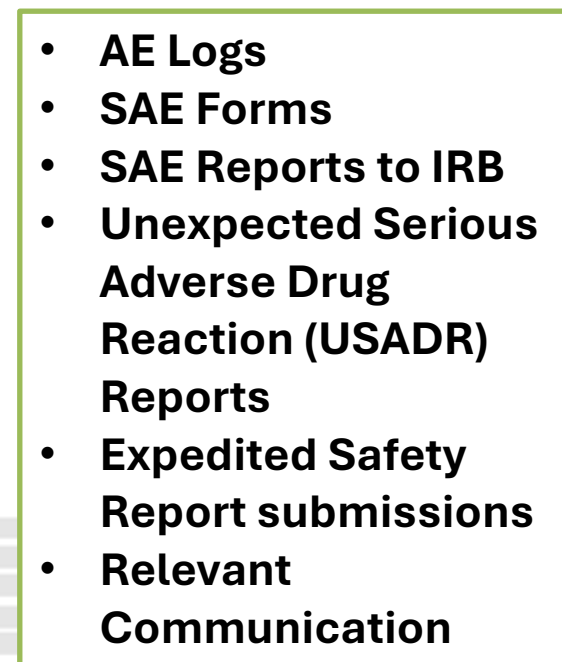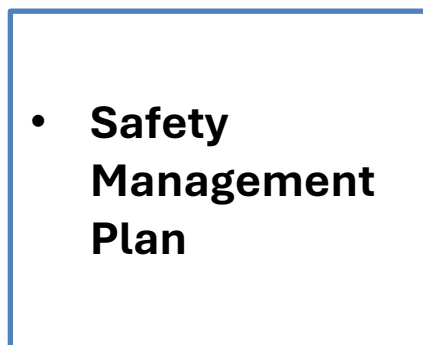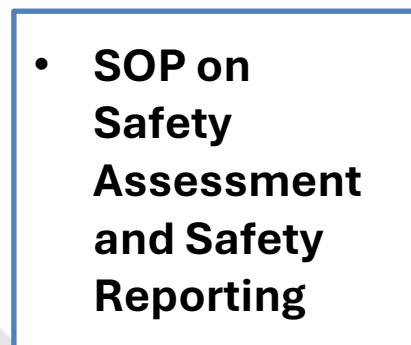
Trial Start-up | **Trial Conduct (FPFV-LPLV)** | Trial Completion

Inputs

[Systems-level]
Sponsor's documented procedures

+

[Trial-level]
Trial-specific documented procedures

→

Outcome

Essential Records

- **SOP on Safety Assessment and Safety Reporting**

+

- **Safety Management Plan**

→

- **AE Logs**
- **SAE Forms**
- **SAE Reports to IRB**
- **Unexpected Serious Adverse Drug Reaction (USADR) Reports**
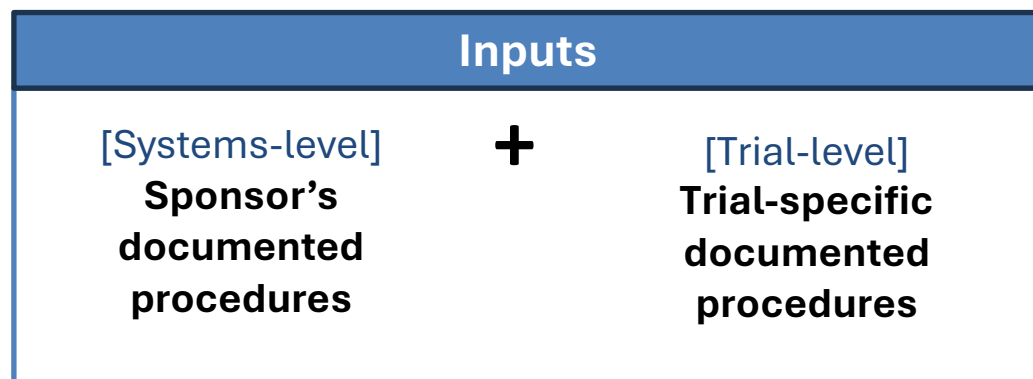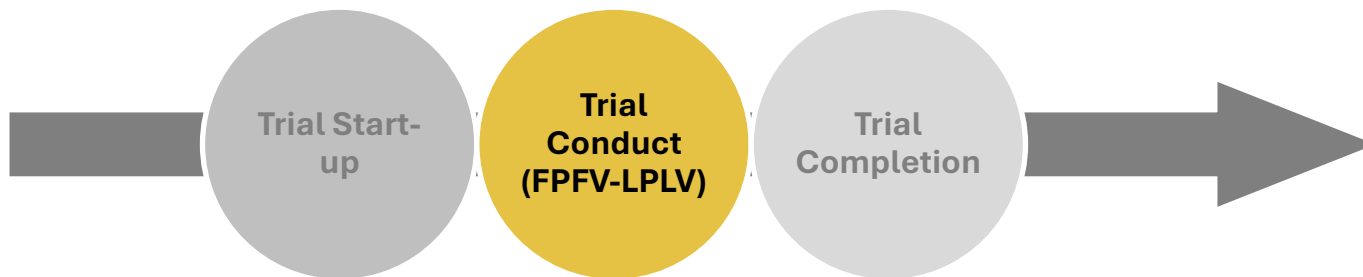- **Expedited Safety Report submissions**
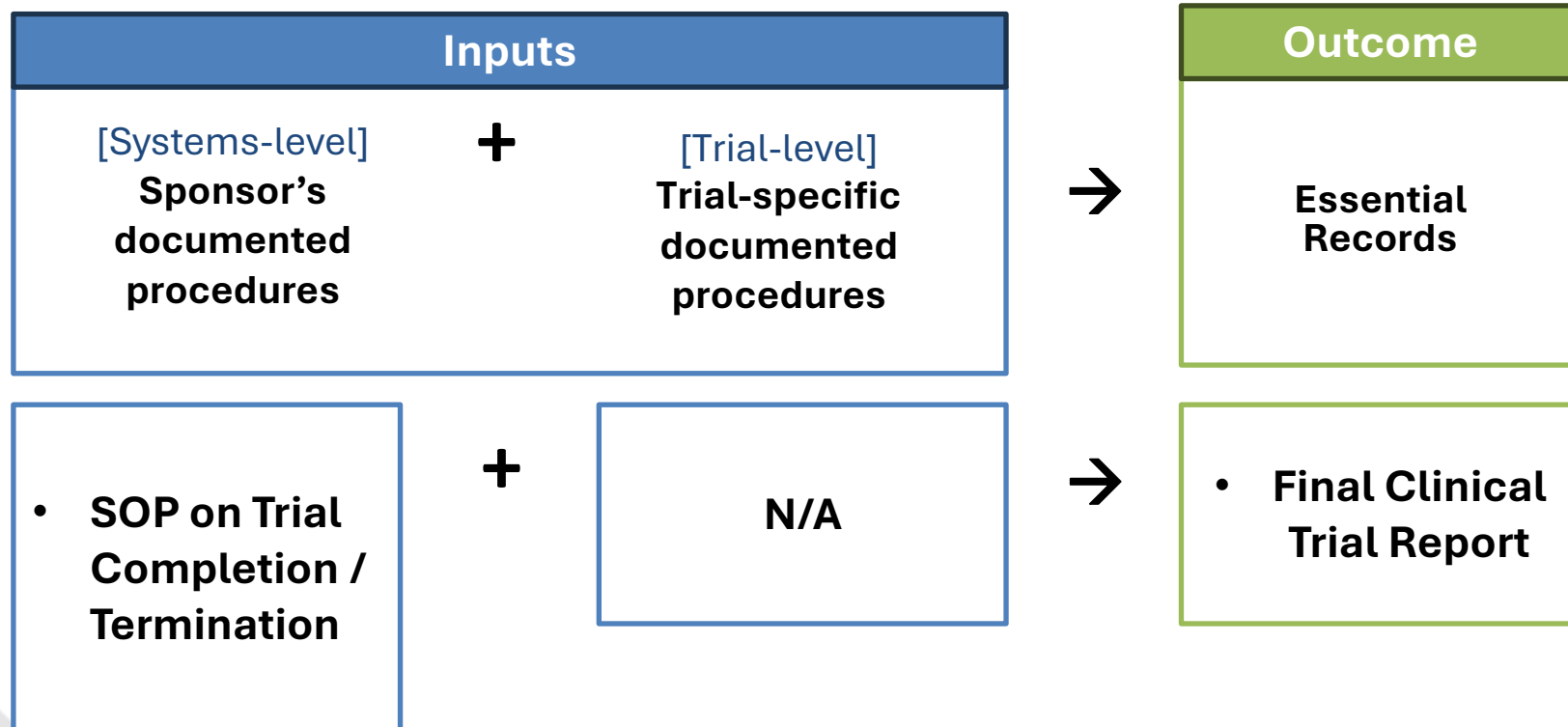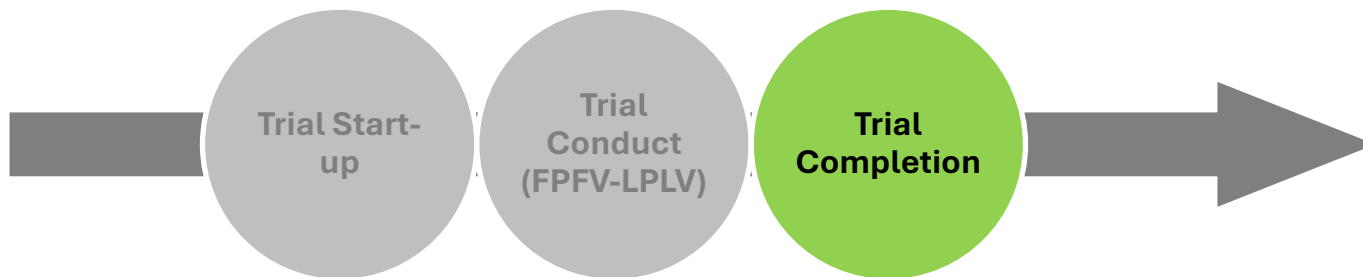- **Relevant Communication**

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Sponsors should assess and determine the appropriate documented procedures based on the nature, scope, and complexity of their clinical trial activities.

Trial Start-up → Trial Conduct (FPFV-LPLV) → **Trial Completion**

Inputs			Outcome
[Systems-level] **Sponsor's documented procedures**	**+**	[Trial-level] **Trial-specific documented procedures**	**Essential Records**
• **SOP on Trial Completion / Termination**	**+**	**N/A**	• **Final Clinical Trial Report**

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Sponsors should assess and determine the appropriate documented procedures based on the nature, scope, and complexity of their clinical trial activities.

Change Control & Training Records

- When updating any documented procedures, it is important to have a formalised **change control process.**
  - **Change initiated → Review → Approval → Communication & Implementation**
  - **Version Number, Effective Date, Revision History Table**

- **Training Records** should be maintained for documented procedures.
  - **Who, What, When, How, Trainer's & Trainee's Name and Signature**
  - Training Records should be readily retrievable and linked to the SOP version to demonstrate compliance.

Tips & Reminders

- Be intentional about how documented procedures are written

- Clearly specify the trial-related roles and activities between sponsor and investigator

- Ensure all interested parties are trained, and maintain training records

- Use Appendix C as a tool to determine which documented procedures are required (Fried Egg Analogy)

- Take a proportionate, risk-based approach in deciding which sponsor-documented procedures are needed for your institution

References

- [Health Products (Clinical Trials) Regulations](#)
- [ICH E6 (R3) Good Clinical Practice (GCP) guideline](#)
- HSA website
  - [Conducting clinical trials](#) [Sponsor]

Thank You!

We welcome your queries!

HSA_CT@hsa.gov.sg