ALMAC

Partnering to Advance Human Health

Fact sheet

Live Study Data Review: IRT Data Monitoring Services



Live Study Data Review

Almac's answer to regulatory requirements for oversight and monitoring of critical IRT data: randomisation and kit assignments.

What are the regulatory views around monitoring of critical IRT data?

Regulatory guidance emphasizes importance of monitoring randomisation data:

The **ICH** indicate key areas for monitoring inclusion are "processes to safeguard essential elements of the clinical trial, such as **randomisation**" (ICH, 2023).

The **MHRA** recommends "checks on **randomisation** processes" (MHRA, 2022) for inclusion in trial's monitoring strategy.

The **FDA** advises including "processes for confirming that **randomisation** is performed according to the protocol and investigational plan" (FDA, 2023) in the **monitoring plan**.

The **EMA** states that documentation demonstrating "compliance with **randomisation** schedule" (EMA, 2018) should be defined as part of the **Trial Master File**.

What are sponsor's responsibilities for monitoring of critical IRT data?

Sponsors responsibilities per regulatory guidance		*Almac's Live Study Data Review*
Sponsors are responsible for determining the extent and nature of monitoring.	*ICH, 2023*	✓ *Almac offers **multiple options** to enable sponsors to select the level of monitoring based on risk / complexity for each trial.*
Sponsors are responsible for ensuring monitoring plan is documented.	*MHRA, 2022*	✓ *Almac's services include documented plan ready for TMF inclusion.*
Sponsors are responsible for ensure monitoring includes reports.	*FDA, 2023*	✓ *Almac's services include monitoring reports ready for TMF inclusion.*
Sponsors may outsource but responsible for oversight.	*FDA, 2013*	✓ *Almac's services are designed to enable oversight, providing visibility of monitoring procedures, plan, and reports.*

Our approach meets current industry trends and regulatory guidance.

What are Almac's Live Study Data Review Services for IRT systems?

There are multiple options made available to sponsors for each data type:

1. Visual Data Review (VDR): sampled data review by Almac support staff.
2. Biostatistics Data Monitoring: statistical review of all data by Almac biostats.
3. Outside of Almac, with Almac support to provide IRT data.

Example of selection of Almac services made by a sponsor:				
Live Study Data Review service	*Data type*			
	Randomisation		*Kit assignment*	
	Included (Yes / No)	*Number of reviews*	*Included (Yes / No)*	*Number of reviews*
1. Visual data review	*No*	*NA*	*Yes*	*3*
2. Biostatistics Data Monitoring	*Yes*	*3*	*No*	*NA*
3. Outside of Almac	*No*	*NA*	*No*	*NA*

Sponsor able to select the service and frequency of reviews.
Selections eligible for mid-study adjustment if required.

What is the difference between Almac's Live Study Data Review Services?

Element	Visual Data Review	Biostatistics Data Monitoring
Responsible roles	DM, PM, Support	Almac Biostatistics
Purpose	Health checks / basic oversight	Statistical monitoring
Study fit	Standard requirements meets sponsor's lower risk classification	Any study simple to complex meets sponsor's higher risk classification
Approach / method	Reduced / sampled monitoring visual data checks on sample of 5 subjects	Statistical monitoring on accumulated data with statistical software by biostatisticians
Sponsor deliverables	PMSD, VDR forms, email notification	BA(s), evidence-based reports, checks and outcomes forms, email notification
Meets regulatory	Oversight / reduced / sampled monitoring	Oversight / statistical monitoring

Almac is uniquely positioned to deliver these services:

- Almac has the Regulatory Knowledge on what needs to be monitored.
- Almac has a comprehensive understanding of IRT functionality and data structure.
- Almac readily have access to the randomisation and kit assignment data!

References

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