EUCROF
European CRO Federation

ADR DATA QUALITY

CRO perspective

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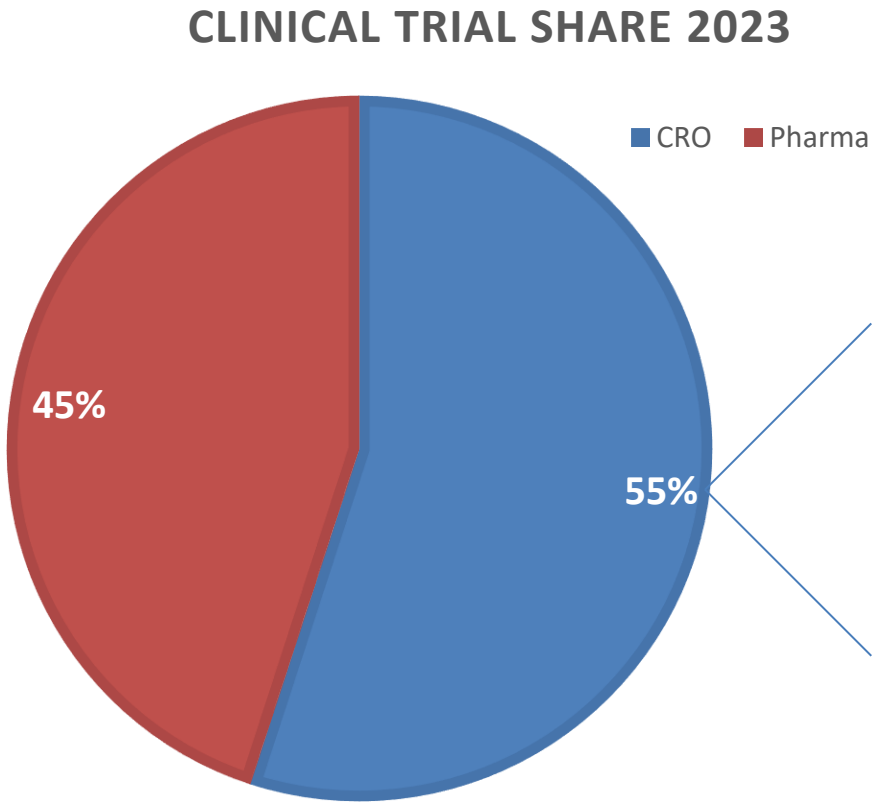
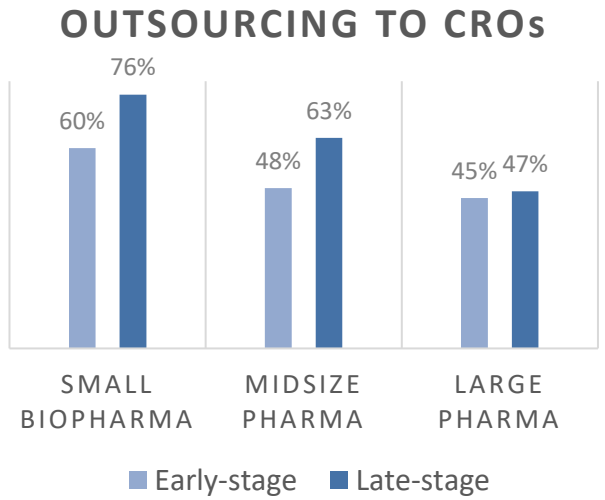
FGK
CLINICAL RESEARCH

Our Agenda for 15 minutes

1. Role of CROs in clinical development and drug safety
2. Main Interfaces in ADR management in clinical trials
3. Current activities to improve data quality in clinical trials
4. Future of data quality

1 Role of CROs in clinical development and drug safety





Source: William Blair CRO Industry Update, Sep-2023

1 Role of CROs in clinical development and drug safety

- Most medium and all big-size CROs have Medical Safety Departments

- Core medical safety package includes clinical monitoring, case management with database, regulatory submissions and periodic benefit risk assessment

- additional medical safety package can include pharmacovigilance and post-market studies (interventional and non-interventional)

2 Main Interfaces in ADR management in clinical trials

Study Site

EDC

Safety Group

Submissions

CHALLENGES

Variability in experience and training level

Clinical database vs Safety Database, Data Security

Trial complexity: several CROs involved in one trial or with different trials; Regulatory changes, Staff recruitment and Retention

Expedited, Periodic, CSR, Dossier

3 Current activities to improve data quality in clinical trials

Study Site

a. It starts with providing clear definitions of safety terminology and expectations in the study protocol
b. Safety Management Plan with ADR collection forms instructions that are study specific, easy to understand and to fill out
c. Continuous training and sensitization of study site and especially PIs starting from the study site initiation and during the study (timely reporting, diagnosis vs symptoms, CTCAE severity grading, etc).
d. The quality of narratives written by study sites are often of big concern but this remains an open question and potential for MM and PI interaction.
e. Monitoring clusters of safety report quality issues that are specific to a study site

EDC

a. Implementing automatic checks in EDC system to highlight to the site apparent typos/inconsistencies
b. Requesting signature/approval of authorized personnel on critical steps in ADR recording
c. Reconciliation

Safety Group

a. Four eye principle in case processing
b. Use of standardized dictionaries to code AEs, CMs and MHx.
c. Use of templates for generation of case narratives
d. Staff training
e. Robust company deviation management

Submissions

a. Four eye principle in preparation of submissions through WebTrader
b. Using gateway submission

4 Future of data quality

Registration and feedback on clinical signs in live mode

Transfer of clinical signs and Processing

Medical Review

Regulatory Submissions

HUMAN OPERATORS

QUALITY CONTROL

4 Future of data quality

Once, we used to search for capable technology – now, we must keep up with the technology advances

What for some is perceived as the future for others is already the past

Relying solely on technology advances isn't the future solution; instead, together with investing in people and enhancing quality methodology.

THANK YOU FOR YOUR ATTENTION!

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Contact us at info@eucrof.eu

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