ISPE GAMP GCP SYSTEMS GOOD PRACTICE GUIDE SECOND EDITION

DRIVERS, UPDATES AND NEW CONTENT

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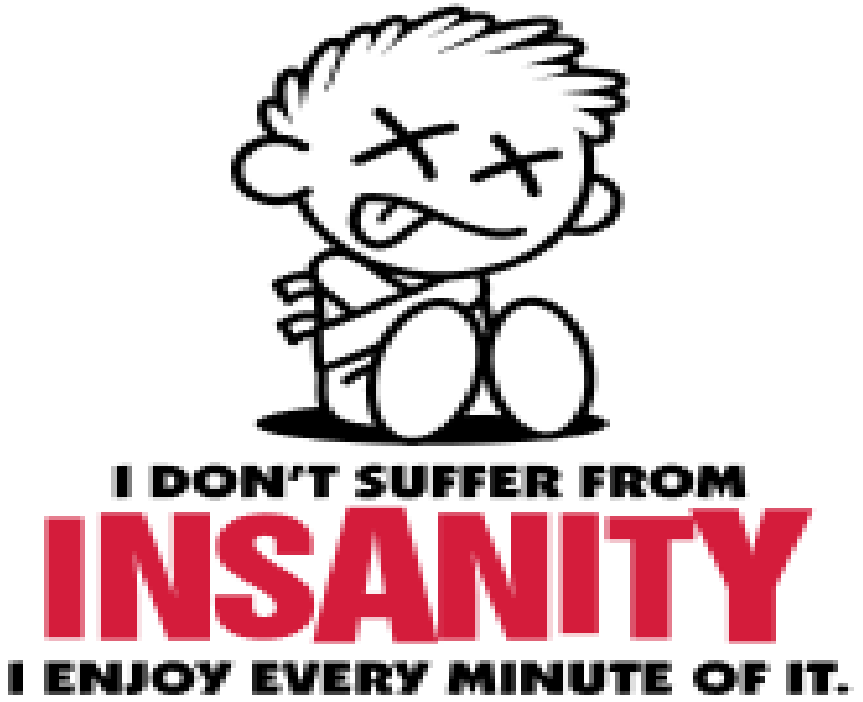
DISCLAIMER

- **The views and opinions expressed in the following presentation represent the opinions of the author/speaker.**
- **ISPE Volunteers created the guide presented. We are proud of our achievement and love talking about it, but there are no financial benefits or incentives.**



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ISPE®

Incorrect configuration
System unavailable
Data Corruption
How many of you had problems with GCP Systems in 2024?

DRIVERS FOR GCP SYSTEMS GPG 2ND ED.

- 1st Edition was published 2017…
- A lot has happened since then, including:
  - Decentralized trails
  - Real-World Data / Real-World Evidence
  - Data Science & AI/ML
- Regulatory updates including:
  - EMA Notice to Sponsors (2020)
  - EMA Guideline on computerized systems (2023)
  - FDA draft CSA guideline (2022)
  - ICH E6 (R3) (2024)
- Alignment with GAMP 5 Second Edition (2022)

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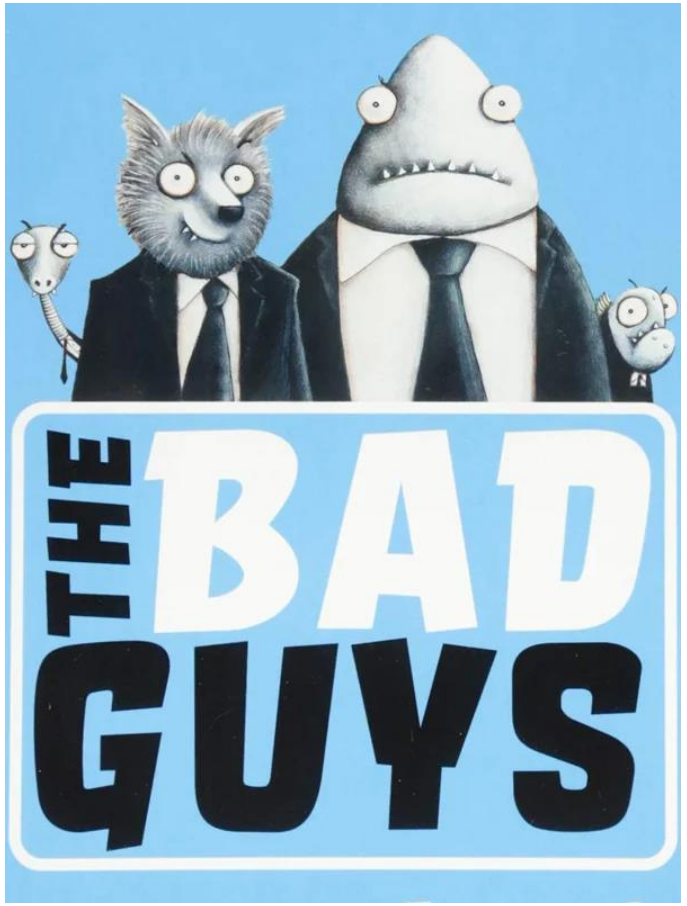
RECENT ISSUES & FINDINGS IN CLINICAL TRIALS

- Acelyrin Phase 3 Failure (2023)
  - …“phase 3 clinical trial unexpectedly failed.“…“a programming error had been identified in one study. Patients in two groups of a study for psoriatic arthritis (PsA) were not dosed as planned.“



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https://www.fiercebiotech.com/biotech/acelyrin-blames-cro-error-shocking-phase-3-failure-sent-shiver-through-biotech-ipo-market

RECENT ISSUES & FINDINGS IN CLINICAL TRIALS

COVID-19 hydroxychl uine study published in La be retracted because th based on Electro cord (EHR) data from inconsis urces, compromising the overall quality of the combined data set.

RETRACTED!

"This research appeared to carry multiple biases."

"The very high homogeneity of the patients' characteristics at baseline was inconsistent with region specific epidemiology and several critical confounding factors."

Hydroxychl be linked y 17,000 death

RETRACTED!

https://www. ct.com/science/article/pii/S07533222301853X

Mehra, M. R., S. S. Desai, F. Ruschitzka, and A. N. Patel. "RETRACTED: Hydroxychloroquine or Chloroquine with or without a Macrolide for Treatment of COVID-19: A Multinational Registry Analysis." *Lancet* (22 May 2020).
Toumi, M., M. Biernikiewicz, S. Liang, et al. "A Critical Analysis and Review of *Lancet* COVID-19 Hydroxychloroquine Study." *Journal of Market Access and Health Policy* 8, no 1 (2020)

STRUCTURE

- Main structure of the 1st Edition remains unchanged:
  - Process Overview
    - Including Clinical Project Layer Model
  - Process Model including e.g.
    - Process steps of eClinical Trials, typical supporting Systems, associated Risks and potential validation approaches.
  - Data Integrity , including e.g.
    - Electronic Source data, signatures, audit trail review and certified copies

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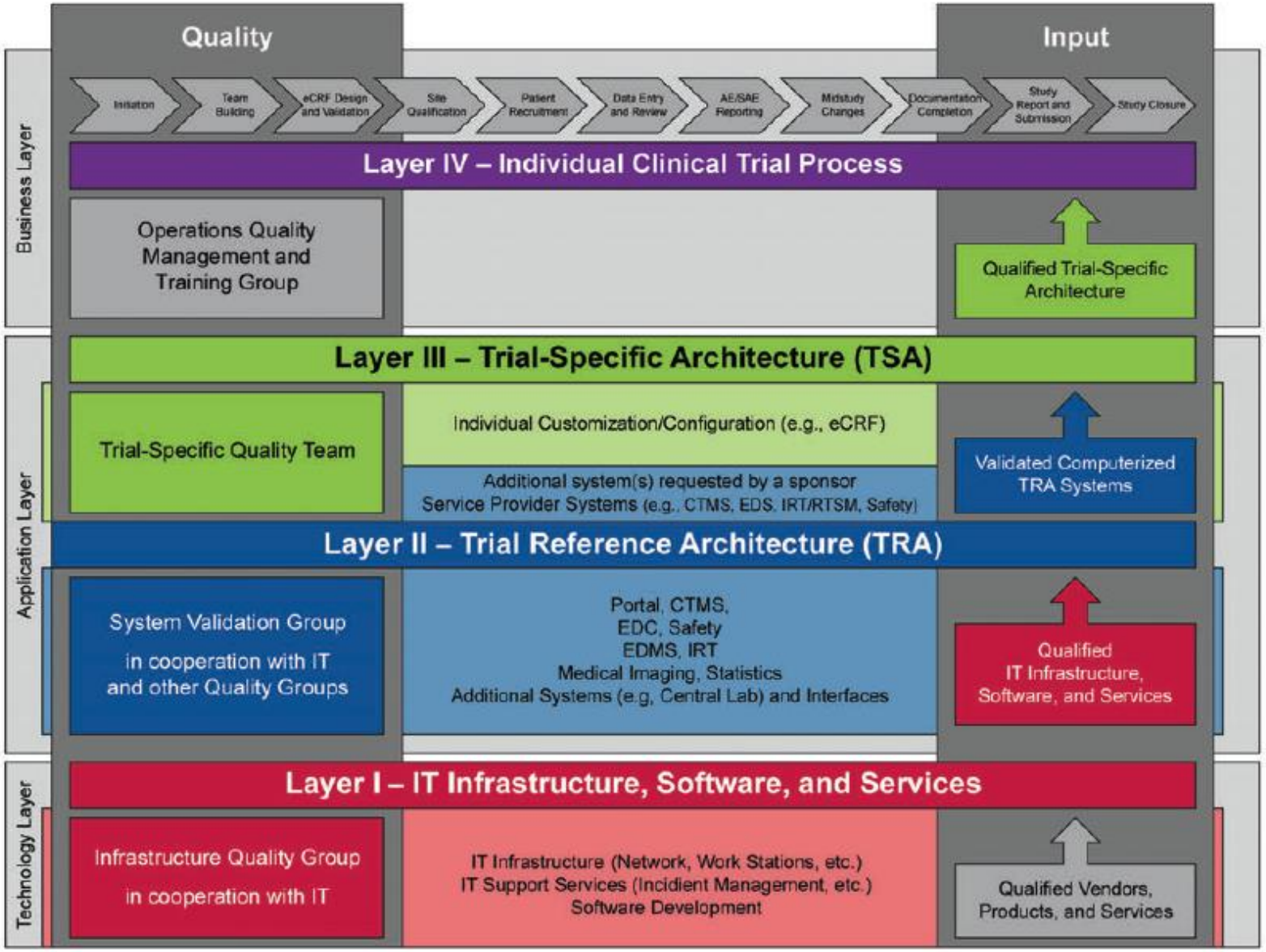
CLINICAL PROJECT LAYER MODEL



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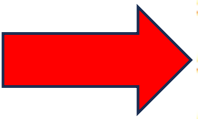
“THE CORE”



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“THE CORE”

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NEW / UPDATED CONTENT

- Data Collection at Clinical Trial Investigator Site Systems
- Oversight Activities, including Audits / Assessments
- Quality By Design & Inspection Readiness
- Quality Risk Management for Setup and Validation of Computerized Clinical Systems
- Appendix Data Privacy
- Appendix Decentralized Clinical Trials
- Appendix Assessment of Clinical Site Systems
- Appendix Good Clinical Laboratory Systems
- Appendix Data Science and AI-enabled Systems
- Appendix Real World Data / Real World Evidence
- Appendix Open Source Software in Clinical Trials

DETAILS

DATA COLLECTION AT CLINICAL TRIAL INVESTIGATOR SITE SYSTEMS

Challenge

"*As part of the site qualification, the sponsor should assess the systems in use by the investigator/institution to determine whether the systems are fit for their intended use in the clinical trial (e.g. include an audit trail). The assessment should cover all computerised systems used in the clinical trial and should include consideration of the rights, safety, dignity and wellbeing of trial participants and the quality and integrity of the trial data.*"

(EMA Guidance on Computerised systems in Clinical Trials, similar requirements are in ICH E6 R3)

Good Practice Guide

More than 20 pages of guidance covering:

- Typical System Landscapes
- Verification and Validation Approach – Site and Sponsor perspective
- Basic requirements for site systems handling eSource data/records
- Leveraging supplier activities and documentation
- Appx: 3 Assessment of Clinical Site Systems

DATA PRIVACY

Challenge

As Clinical Trials capture data from participants, the privacy of these data must be ensured. In GCP terms, data privacy is one aspect of the trial participant's well-being. What factors should be considered as part of the computerized system lifecycle to ensure compliance with data privacy laws?

Good Practice Guide

Detailed guidance covering:

- Key Regulations & Definitions
- Clinical Data and Personal Data
- Data Pseudonymization/Anonymization
- Roles and Responsibilities
- Vendor management
- International data transfers
- Privacy by Design

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HIPAA

Protect Patient Information

DECENTRALIZED CLINICAL TRIALS

Challenge

Decentralized Clinical Trials (DCTs) bring all or part of the study to the patient, such as their home, local healthcare facility, or laboratory, making it less challenging for patients to participate in clinical trials. The goal is to minimize the patient burden while accumulating real-time, accurate clinical trial data. But how can we manage e.g. IMP delivery, monitoring, audits, privacy and blinding?

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Good Practice Guide

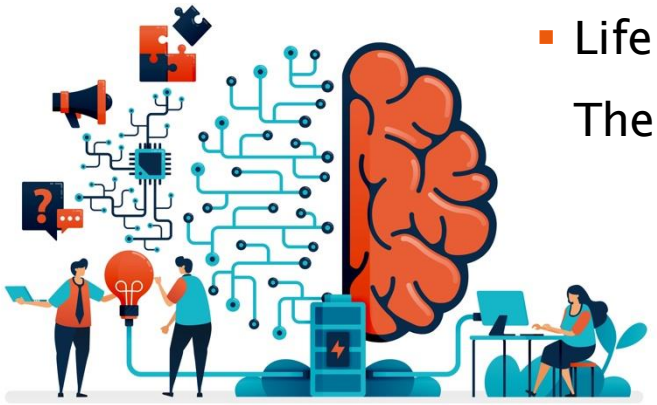
Detailed guidance covering:

- Definitions & Regulations
- Technical Considerations
- Site Feasibility
- Digital Health Technologies and Devices
- Training
- Investigational Medicinal Product aspects

DATA SCIENCE AND AI-ENABLED SYSTEMS

Challenge

The growing amount of clinical data forces the evolution of clinical data management towards clinical data science, adopting data analytics approaches, including emerging technologies like AI/ML. How can these systems be implemented and used in a compliant way?



Good Practice Guide

Detailed guidance covering:

- Overview on AI/ML Concepts
- Overview of Standards and Regulatory Guidance
- Evolution from Clinical Data Management to Clinical Data Science
- Maintaining data integrity and quality
- Limitations and Ethical Considerations on AI
- Life Cycle Model / AI-enabled Commercial Off-The-Shelf Systems and Pre-Trained Models

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REAL WORLD DATA / REAL WORLD EVIDENCE

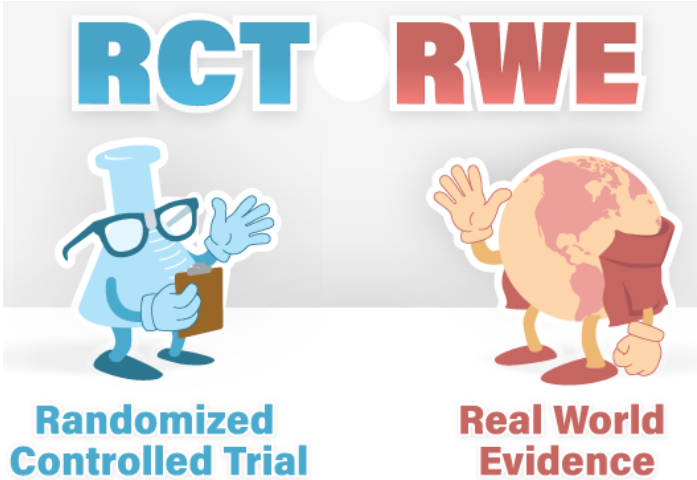
Challenge

Real-World Data (RWD) and Real-World Evidence (RWE) from sources such as electronic health records (EHRs), have gained significant importance in e.g. Evidence Generation, Site selection and Personalized Medicine and Precision Health. But how can we control data quality, data privacy and bias while establishing reproducibility, transparency and regulatory acceptance?

Good Practice Guide

Detailed guidance covering:

- Definitions and Regulations
- Potential uses of RWD and RWE
- RWD/RWE Process and Data Validation
- Data Accrual
- Selection of Data Sources
- Data Preparation and Curation
- Data Privacy Aspects
- Data Retention



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OPEN-SOURCE SOFTWARE IN CLINICAL TRIALS

Challenge

How can open-source software such as:

- Data Capture via EDC systems (e.g. RedCap, openEHR)
- Statistical Analysis (e.g. RStudio)

be implemented and validated?

Good Practice Guide

Detailed guidance covering:

- GCP Relevance of Open-Source Software
- License models
- Regulatory Positions
- Security
- Risk Management & Validation

REDCap
Research Electronic Data Capture

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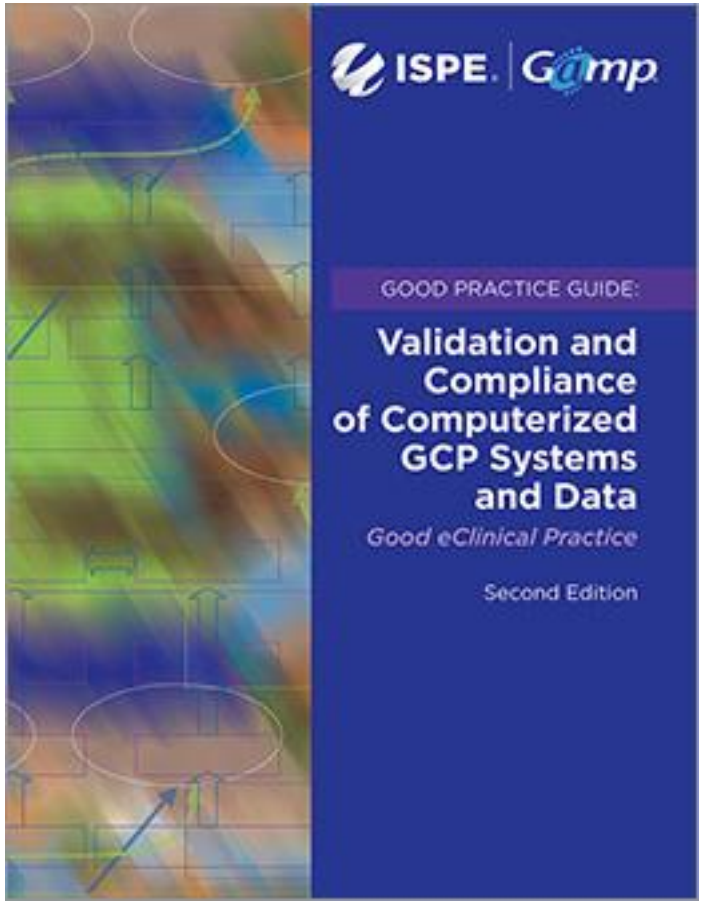
openEHR

RStudio®

THERE'S NO SUCH THING
AS A FREE LUNCH.

HOW TO GET THE GUIDE…

- https://ispe.org/publications/guidance-documents/gamp-good-practice-guide-computerized-gcp-systems-data-2nd-edition
- You get
  - **250+ pages** of content
  - created by an international group of **50+ industry experts**
  - has gone through extensive **industry and regulatory reviews**
  - is aligned with the **industry-leading CSV Guidance GAMP 5**
  - has been professionally edited.



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We reduce risks.