GAMP ACTIVITIES

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Immediate Past-Chair, GAMP America's

GAMP Trainer, ISPE

2023 Richard B. Purdy Distinguished Achievement Award Recipient

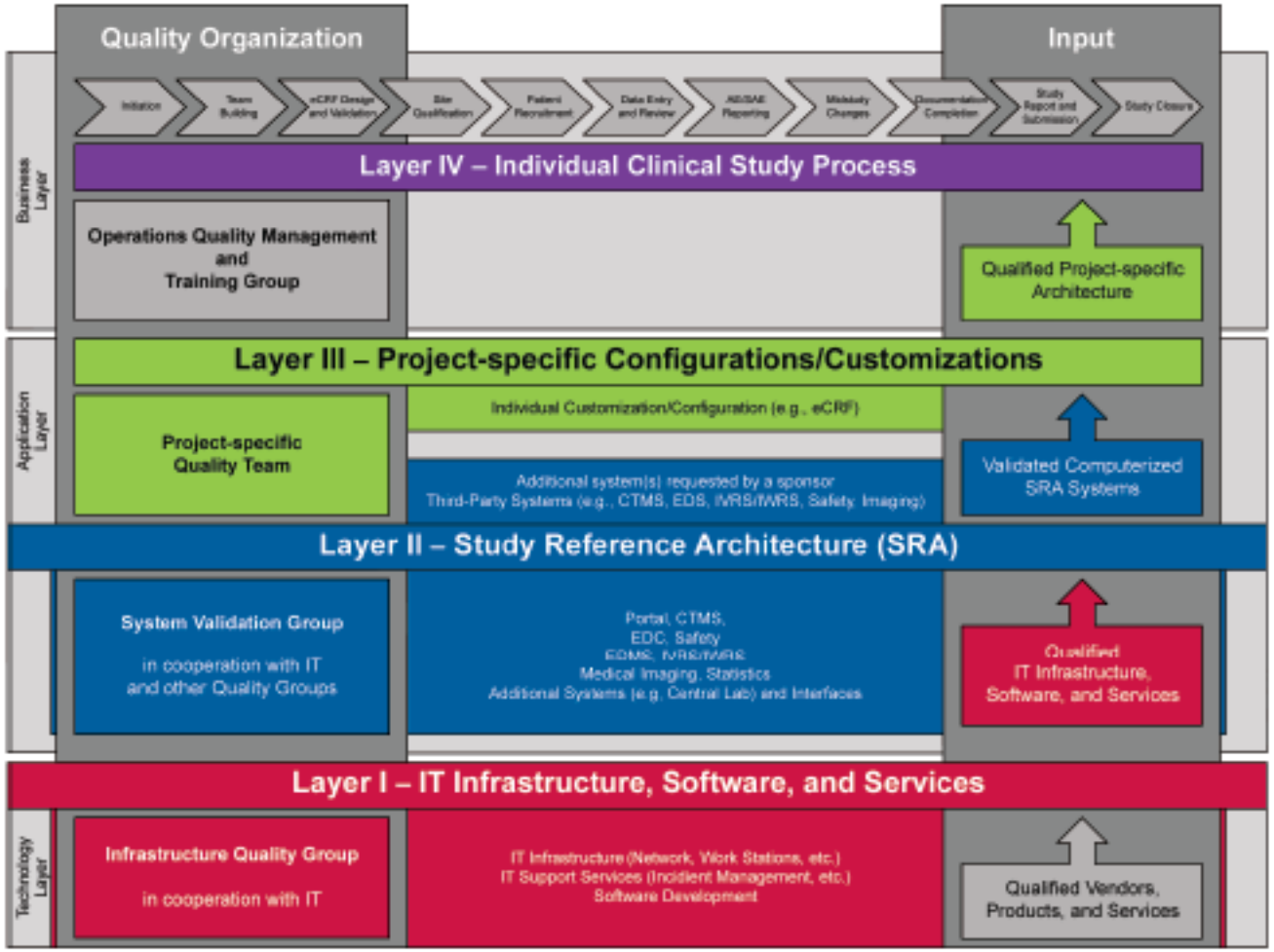
Co-Chair GAMP CSA Special Interest Group

Member, GAMP Global Steering Committee – recipient of the 2022 ISPE Committee of the Year Award

Recent Drivers in Clinical Trials

- COVID 19
  - Decentralization
  - Real World Data(RWD)/Real World Evidence (RWE)
- Regulatory Updates
  - Notice to Sponsors
  - Guideline on computerised systems and electronic data in clinical trials

Clinical Project Validation Layers - Overview



GAMP Good Practice Guide Validation and Compliance of Computerized GCP Systems and Data 2nd Edition

SCHEDULED FOR PUBLICATION IN JULY 2024

Ch 01 Introduction

Ch 02 Scope

Ch 03 Regulatory Overview

Ch 04 Process Overview

Ch 05 Process Model

Ch 06 Data Integrity

Appendix 1 Data Privacy

Appendix 2 Decentralized Clinical Trials

Appendix 3 Assessment of Clinical Site Systems

Appendix 4 GCLP

Appendix 5 The Use of Data Science - AI enabled Systems

Appendix 6 RWD RWE

Appendix 7 Open Source Software

MORE THAN 180 PAGES OF NEW CONTENT!

GAMP Good Practice Guide
Validation and Compliance of Computerized GCP Systems and Data

This eClinical Good Practice Guide aims to highlight a common approach for application and discuss or address the differences in system validation practices between the GMP, GLP, or other GXP areas and GCP environments.

This document is intended to adapt the general principles of ISPE GAMP®5 Second Edition [3] to the systems supporting the conduct of clinical trials and addressing applicable GCP (inter)national regulatory requirements. It provides a detailed interpretation of the GAMP validation concepts and enables a consistent and standardized application of the risk-based validation approach and principles to processes and their supporting computerized systems when conducting clinical trials.

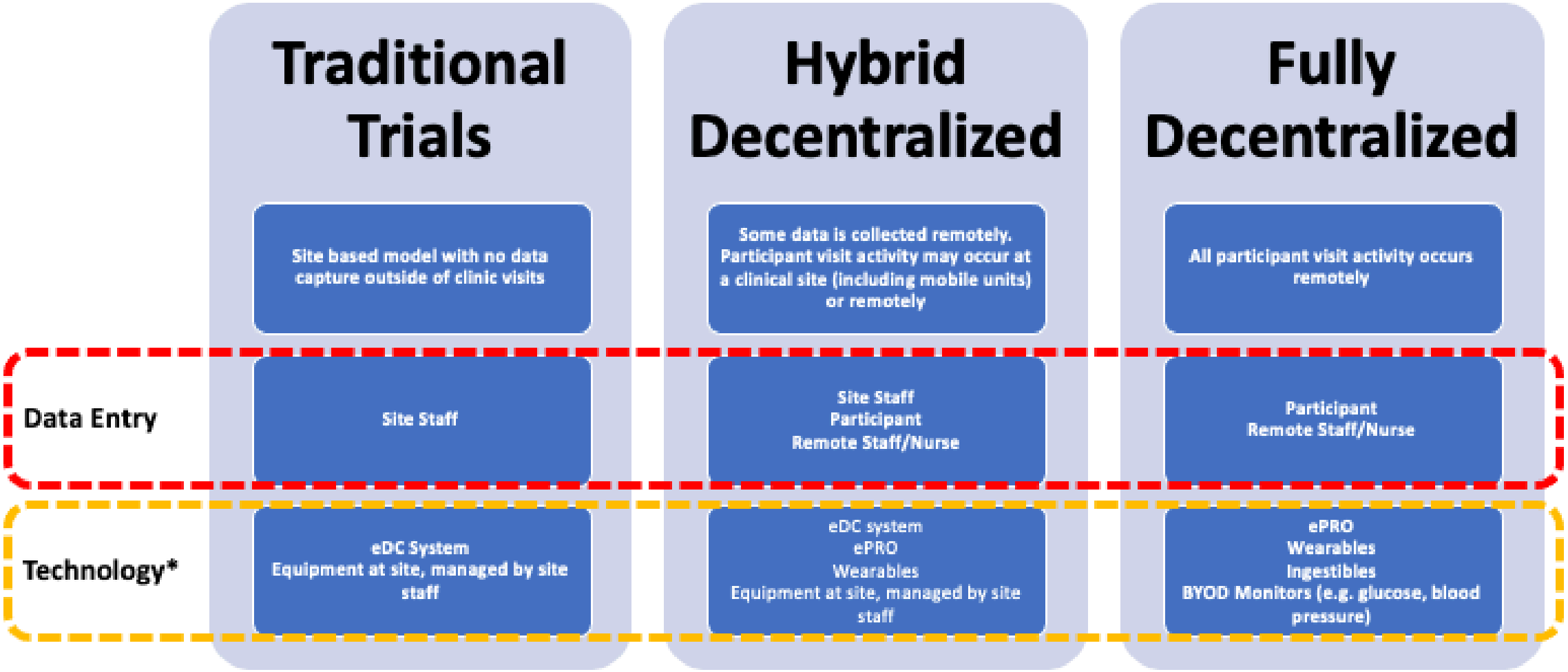
This Good Practice Guide facilitates the effective and efficient use of valuable resources by the application of appropriate and proportionate practices, encouraging innovative approaches to managing risk to patient safety, product quality, and data integrity while supporting benefit to public health. It is not a prescriptive method or standard but rather provides pragmatic guidance approaches and tools for the practitioner. When applied with expertise and good judgment this good practice guide offers robust cost effective approaches.

Guidance on the Life Cycle of Computerized GCP Systems

This Guide aims to provide guidance on the life cycle of computerized GCP systems, including:

1. Understanding the business process supported by computerized systems
2. Understanding the unique risks associated with clinical data
3. Understanding the complex issues of managing computerized systems on a variety of infrastructure platforms at different version levels across multiple organizations
4. Suggesting possible validation approaches, system classifications, and challenges
5. Ensuring compliance with applicable regulations with a particular emphasis on data integrity and dataflows considering challenges through outsourcing of services and technology

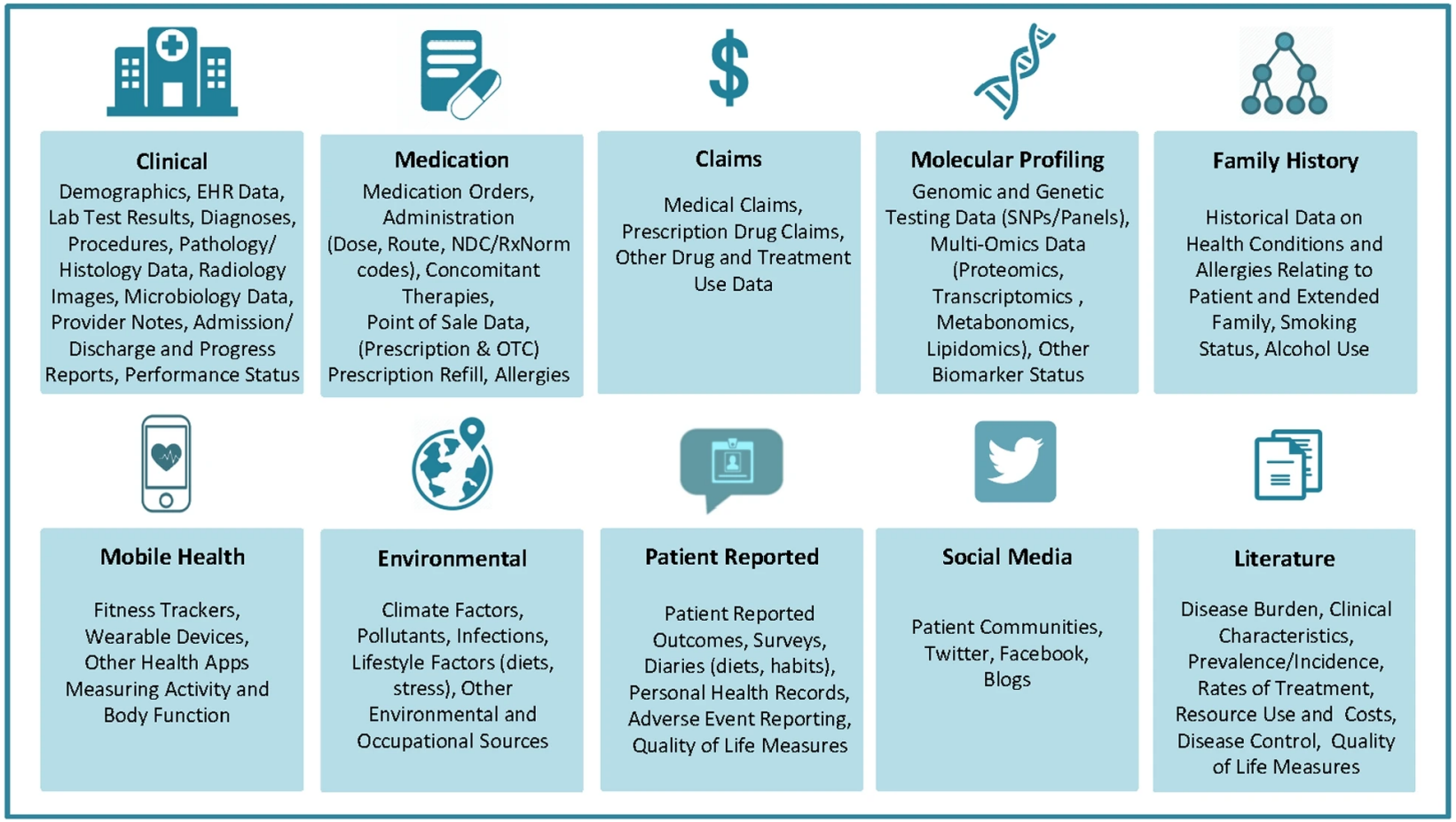
Decentralized Clinical Trials



* Example of technologies, but not limited to these

Real World Data – Real World Evidence

- RWD is typically collected and aggregated for specific, non-regulated purposes but evaluated and used in a regulated context e.g. in clinical trials or Pharmacovigilance
- There have been more than a dozen New Drug Approvals in the last 10 years that utilized RWE



RWD/RWE and GAMP

If RWE is used in a regulated context, the processes and tools used to generate the RWE should be validated.

- Definition of the business question to be answered for intended use of the RWE (e.g., for clinical trials, reimbursement, drug safety)
- Selection of the research approach (e.g., noninterventional study, analysis of social media) and Data source (e.g., EHR systems, product and disease registries)
- Methodology (e.g., population, exposure, and outcomes of interest)
- Approach to identify and minimize Bias

GAMP Special Interest Groups – Global SIGs
New members and Emerging Leaders are encouraged to join

Software Automation & AI

To explore, educate, and bring regulatory/compliance awareness of innovative technologies such as software automation (ex. RPA) and artificial intelligence (ex. ML) to the pharma and biotech industry.

Eric Staib eric.staib@syneoshealth.com
Brandi Stockton bstockton23@outlook.com

Blockchain

To help enable the adoption of blockchain technology in regulated environments by exploring use cases, sharing lessons learned, and contributing to thought leadership around this topic.

Jamey Canterbury jamescbury@proton.me
Tanya Sharma Tanya.sharma@assureallc.com

Cloud

To provide industry guidance and establish clear roles and responsibilities for the use of Cloud solutions in regulated (e.g., GxP) space.

Anders Vidstrup anders@vidstrup.dk
Anette Westphal awe@novonordisk.com

Risk Management SIG

To research, explore and propose new models, tools and approaches based on the latest technologies and innovations in the data science and computing areas (i.e., AI, ML) that can be applied to the Quality Risk Management process to make it more objective, predictive, and efficient in order to protect patients' safety and health.

Anne Woitzik Anne.Woitzik@kvalito.ch
Filip Raps Filip.raps@glpg.com

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CSA

To develop practical approaches to optimizing validation activities through increased focus on Quality Risk Management and critical thinking in line with FDA's Case for Quality and GAMP 5 Second Edition.

Charlie Wakeham charlie.wakeham@wakeuptoquality.com
Lorrie Vuolo-Schuessler lvschuessler@Verizon.net

Agile

To illustrate how Agile software development practices can be used in support of the validation of GxP regulated computerised systems.

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Donal O'Brien Donal.Obrien@3ds.com

MES

Define industry best practices for MES project initiation, planning, execution and operations by establishing a silo breaking collaboration of vendors, industry manufacturers, Quality organizations, consultants and regulators and all involved stakeholders.

Christian Woelbeling christian.woelbeling@werum.com
Mark Wager wager_mark_j@lilly.com

eClinical

To provide market support for all validation aspects related to computerized GCP system, including understanding the business process and the unique risks, enabling innovation and managing the complex computerized systems across a variety of infrastructure platforms and organizations. Working to update eClinical Guide.

Oliver Herrmann oliverherrmann@q-finity.de
Max Stroebe mstroebe@its.jnj.com

GAMP Speakers at ISPE Annual Meeting

- **Sunday 13 October - Technology in Alignment with EU Guidance & eClinical GPG eClinical Workshop**

Petch Ashida Druar – Syneos
Brandi Stockton – The Triality Group
Lorrie Vuolo-Schuessler – Retired
Geetu Abbi – Alkermes

- **Monday 14 October - Overcoming Challenges of Digital Innovation (AI)**

Brandi Stockton – The Triality Group
Eric Staib - Syneos

- **Monday 14 October – Digital Tools Presentations & Panel Discussions**

Ken Shitamoto – Gilead Sciences
Stephen Ferrell - Strikegraph

- **Tuesday 15 October – Computerized Systems Quality**

When it Happened: Considerations in Disaster Recovery
Frank Henrichmann - QFINITY

Is the EMA GCP CSV Guideline a blueprint for other GxPs?
Oliver Herrmann – QFINITY

- **Tuesday 15 October – AI Discussion Panel – Reflections on Past Missed Opportunities (QbD, PAT) and How to Navigate AI for Success**

Brandi Stockton – The Triality Group


QUESTIONS