Maximizing Outcomes Through Multi-Site Study Collaboration

Sue McPherson
Executive Director, Safety Assessment
WuXi AppTec, Laboratory Testing Division

Ken Schafer
Greenfield Pathology Services, Inc.

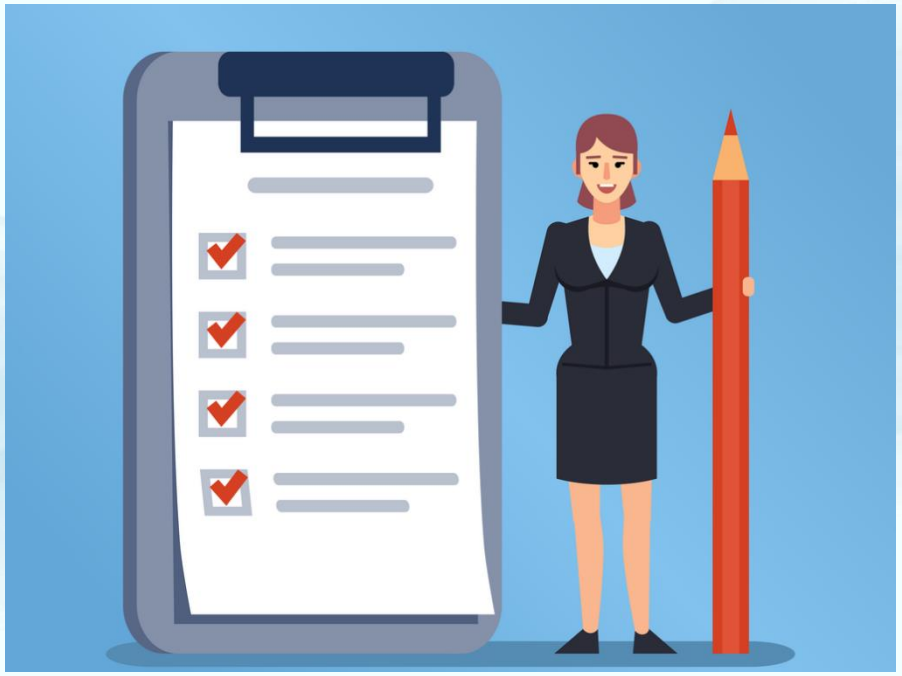
Presenters

Sue McPherson
Executive Director
Safety Assessment
WuXi AppTec, Laboratory Testing Division

Ken Schafer
Greenfield Pathology Services, Inc.

AGENDA

- Introduction
- Conduct
- Management and Control of Multi-site Studies
- Conclusion
- The View from the Other Side
- De-Mystifying Multi-Site Studies: Pathology Perspective



WHAT IS A MULTI-SITE STUDY

Definition

- A GLP study conducted across multiple locations is known as a multisite study.

Unified Study Compliance

- Although performed at different sites, it remains a single study and must fully comply with GLP principles.

Key Success Factors

- *Planning* – Detailed, strategic organization of all study activities.
- *Organization* – Clearly defined roles, responsibilities, and protocols.
- *Communication* – Ongoing coordination among all sites.

Distinct Locations

- Sites may vary *geographically* or *organizationally.*

WHY CONDUCT A MULTI-SITE STUDY?

- There may be a need for specialized services that the facility lacks or does not have the expertise to provide
- Typical areas when multi-site studies are conducted include but not limited to:
    - Dose formulation analysis
    - Bioanalysis
    - Specialized investigations (genomics)
    - Pathology

RULE OF ONE

Remember the "rule of one": Even in a multisite study, it remains a single study with a unified study plan/protocol, one final report, and must comply with GLP principles as a single entity.

MULTI-SITE STUDIES

- In the past, multi-site studies were often approached with apprehension and viewed somewhat negatively.
- However, challenges tend to emerge when studies are poorly planned, and communication is lacking.

MULTI-SITE STUDIES

- Careful planning, along with clearly defined lines of communication and responsibility, is essential.

- Effective communication among all partners is critical to conducting a study that meets the highest quality standards.

SETTING UP A MULTI-SITE STUDY

Study Director (SD)

- Central point of control located at the test facility

The Principal Investigator (PI)

- Responsible for the conduct of the defined phase of the study on behalf of the SD

SETTING UP A MULTI-SITE STUDY

KEY PRINCIPLES FOR MULTI-SITE STUDIES

Establish Partner Roles and Protocol

Define partner relationships in advance and document in the protocol/plan.

Responsibilities

Test Facility Management: Holds overall responsibility for the study.

Test Site Management: Responsible for all study activities at their site.

Study Director (SD): Acts as the single point of control.

Communication & Protocol Adherence

All sites must keep the SD informed of study progress.

Any amendments to the plan require SD approval.

Plan deviations must be acknowledged by the Principal Analyst (PA) and promptly communicated to the SD.

Quality Assurance (QA)

QA supervision must be maintained throughout the study.

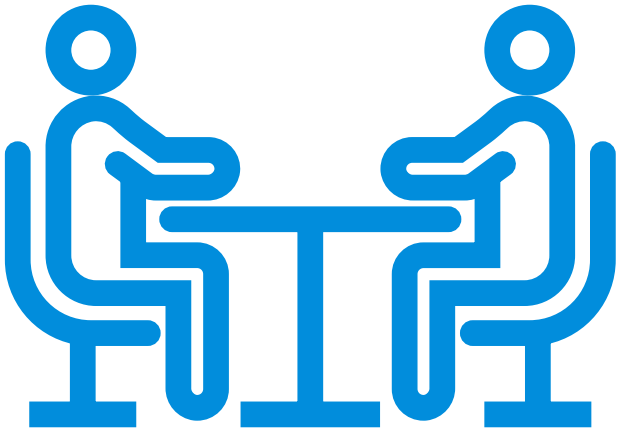
Observations by the test facility or test site QA must be reported to the SD and facility management.

The “Rule of One”

One protocol, one report.

SUBCONTRACTING MULTI-SITE STUDIES

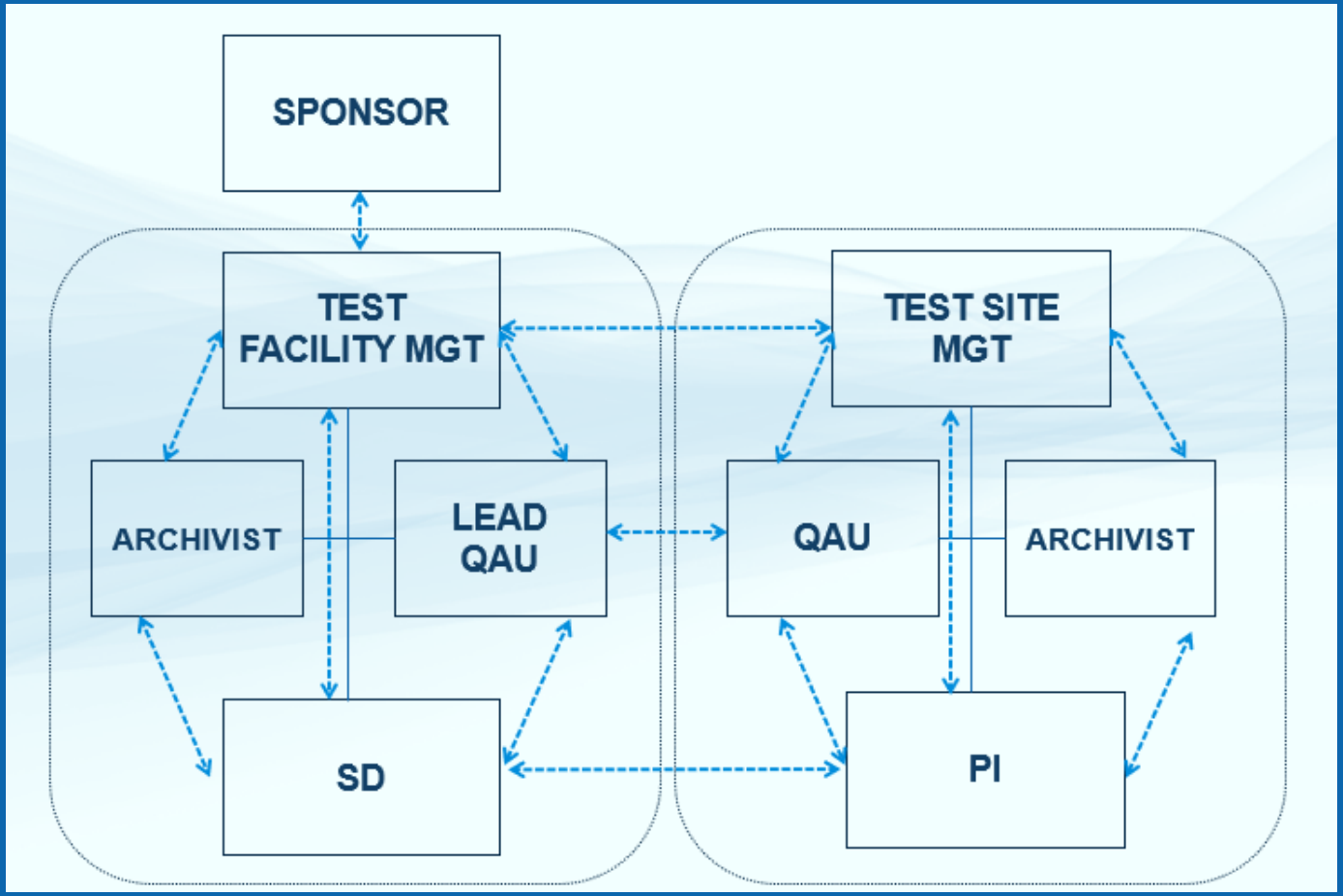
- Ensure the subcontracted test site is fully GLP-compliant.
- Clearly document the scope and responsibilities of the subcontracted work in the study protocol.
- Establish consistent communication between the main facility and the subcontracted site to ensure alignment with study goals and timelines.
- QA oversight should cover both the main facility and subcontracted site for consistent GLP standards.
- The communication triangle among test facility MGT, SD,QA is vital for the success of the study.



SUBCONTRACTING MULTI-SITE STUDIES

Subcontracting part of a multi-site study to a fully GLP compliant test site

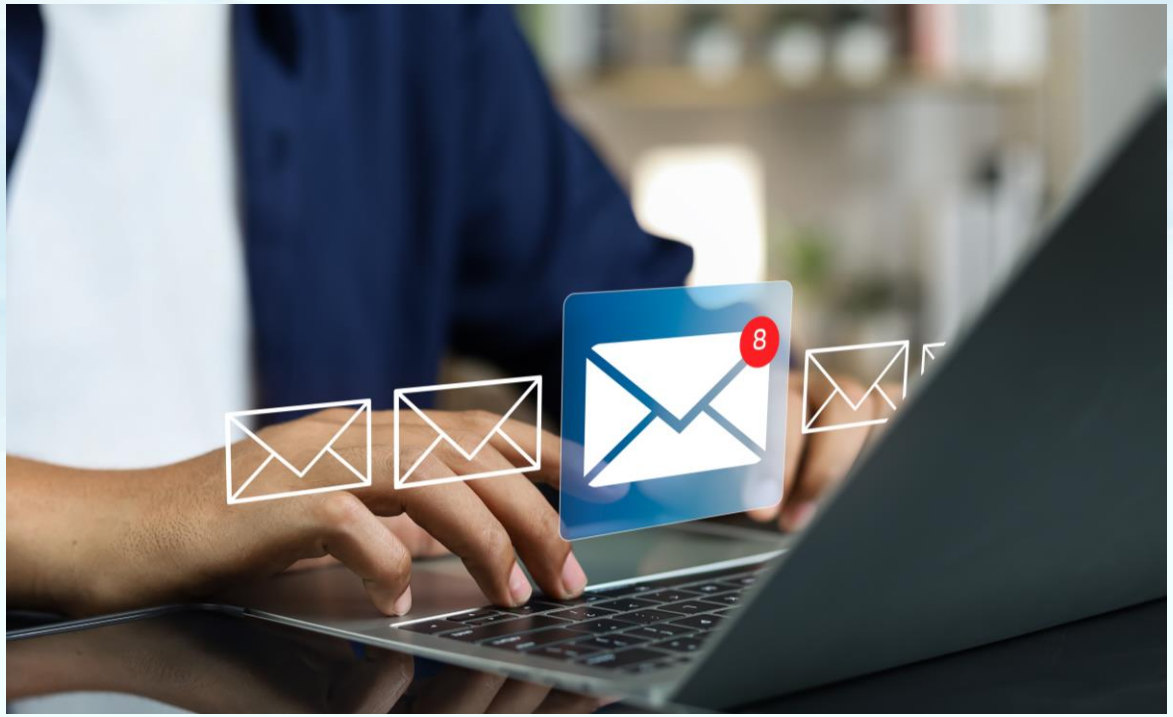
There are many organization aspects of a multi-site GLP study when subcontracting to a fully GLP compliant site



COMMUNICATION

Vital for the success of the conduct of the study

- Notification of Protocol and PA
- QAU findings from test site



CONCLUSION

- Don’t fear multi-site studies
- GLP Principles: RULE OF ONE
- Must have effective planning & communication
- The communication triangle of test facility MGT, Study Director and QAU is vital

EXPAND YOUR POOL OF EXPERTISE

De-Mystifying Multi-Site Studies: Pathology Perspective

Ken Schafer
Greenfield Pathology Services
kschafer@gfpath.com

Greenfield Pathology Services, Inc.

MULTI-SITE STUDY

- Greenfield Pathology Services
  - By definition, GPS is always part of a multi-site study
  - GPS serves as a GLP-Compliant Test Site
  - Remote from the Test Facility (usu. where the vivarium is)
  - It can be important that your Remote Pathology Group have a working relationship with the Test Facility
- You can have a quality histopathology evaluation with a Test Site supporting a Test Facility
- You can leverage global expertise with a Multi-Site Study
- Some Test Facilities have Pathologists in multiple locations, including internationally

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MAINTENANCE OF GLP STATUS?

- Remote Pathologist affiliated with a GLP compliant organization
  - Serves as a Principal Investigator (PI)
- SOP review – Test Facility and Test Site
- Training on Pathology system used
  - Can be either Test Facility or Test Site
- QC responsibilities
- QA responsibilities
- SEND Package

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MULTI-SITE STUDY PROCESS

- Protocol shared with the Study Pathologist
  - Serves as a Principal Investigator (PI)
- Study Pathologist acknowledges receipt and reading/understanding of the protocol and amendments
  - PI Form Completed as Documentation
  - Occurs prior to commencement of any study related work
  - Triggers initiation of study tracking on MSS

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MULTI-SITE STUDY PROCESS (2)

- Study Pathologist receives slide shipment, associated data
  - Organ weights; Necropsy information; Clinical Pathology; In-life tables
  - Received via secure email
  - Slides shipped via courier – All Spp, including NHP
  - Shipping is not something to be feared
  - Both the Test Facility and Test Site need to have experience shipping internationally

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MULTI-SITE STUDY PROCESS (3)

- Pathologist gets to work!
  - Slide evaluation and Microscopic finding entry
  - Test Facility Provantis OR Test Site Pristima
  - Seamless reporting/SEND package generation with Test Facility Provantis
- GPS RAs perform QC of Pathology report and tables
- Report forwarded to Study Director for review and comment
- Report forwarded to Sponsor for review and comment
- Pathologist addresses SD/Sponsor comments
- Test Facility QA inspection – Pathologist address QA comments
- All materials sent to Protocol-designated Archive (China, US, Other?)
- Electronic or Wet Report signature

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ADVANTAGES

- Cost savings of using an experienced partner
- Time savings of study start – especially for NHP studies
- Pathology Resource used may depend on Sponsor's Regulatory Agency submission target
- The Sponsor can leverage Pathology Specialty Expertise globally
  - Primary Pathology Evaluation
  - Pathology Peer Review
  - ACVP – Anatomic or Clinical Pathology Boarded available
  - Tissue/Organ Specific Expertise
- There are experienced Histopathology Vendors that can easily support Multi-site Studies

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