Best Practices of Communication: How to Communicate with Your CRO and/or Client

Kristina DeSmet, PhD, DABT
Associate Director, Toxicology, United Therapeutics

Amy Mihalchik-Burhans, PhD, RAC
Consultant, Gad Consulting Services

Saurabh Vispute, PhD, DABT
Senior Scientist, Pfizer

Best Practices of Communication: A Project Toxicologist's Perspective

Kristina DeSmet, PhD, DABT

Associate Director, Toxicology, United Therapeutics

Selecting a CRO

- Identify key questions to be answered
  - General toxicology capabilities
  - Specialized capabilities
  - Ability to develop a new process/procedure
  - Sites available
  - Volume of work being conducted at preferred sites
  - Scheduling forecast
- Ask to speak with subject matter expert(s)
- Trust your gut

Communicating with your Business Development Representative and/or Client Manager

- Will be point of contact for service requests and general questions
- Request a quote
  - Be as specific as possible
    - Compliance
    - Species and strain
    - Dose formulation preparation
    - Dose formulation analysis
    - Route of administration and dosing regimen
    - Experimental design
    - Endpoints
    - Reporting
  - Payment schedule
  - Milestone and corresponding date final report(s) and SEND dataset(s) are required

Communicating with your Study Director

- Point of contact for studies
- Pre-study/protocol development phase
  - Introductions
  - Discuss purpose of the study
  - Provide relevant information about test article and overview of project
  - Are there any special considerations that need to be addressed
  - Establish preferred communication plan
  - Establish process (internal) for saving study-related communications
- In-life phase
  - Onsite monitoring
  - Study updates
  - Emergency communications
  - Documentation of changes to protocol

Communicating with your Study Director

- Reporting phase
  - Stay in communication with SD
  - Reiterate current timelines and convey any changes
  - SD will serve as point of contact between Sponsor and Individual Scientists at the CRO
  - If Sponsor-designated CRO is being used for sample analysis, ensure that predetermined timelines will be met
  - Align with SD on overall assessment of safety and NOAEL

- After the report is finalized stay connected

Best Practices of Communication: A Consultant's Perspective

Amy Mihalchik-Burhans, PhD, RAC

Consultant, Gad Consulting Services

Why Consider a Consultant?

- Consultants may perform two primary functions
  - Act as an additional SME to fill gaps in a program
    AND/OR
  - Provide a “bird’s eye view” of a program
- Streamline interactions between all stakeholders involved
  - Organize (competing) timelines
  - Encourage efficient communication between parties
- Define a program within appropriate regulatory context
  - Determine best regulatory path forward as program evolves
  - Troubleshoot program as data are generated

Role of a Consultant

- Understand the goal(s) of the client and limitations
  - Focus on what can be achieved with the resources (including time) available to the client
  - Know your role in the “grand scheme”
  - Is the client small/mid/big pharma – each has different needs

- Establish parameters of the project EARLY and OFTEN
  - Miscommunication costs time, money, and trust
  - Make sure to address overall scope, timeline, expectations, data sharing protocols, and expected deliverables
  - Keep written records of project progression (i.e., document calls and collate separate email chains)

Communication Strategies as a Consultant

- Establish client preferences – email, telecon, virtual, or in-person meetings?
- When preparing deliverables, strive to be:
  - CONCISE
  - DIRECT
  - CLEAR
- Keep the intended audience in mind
  - What is pertinent?
  - How should I present this?
  - Where will this be distributed?

Manage Expectations (and Timelines)

- Consultants are not there to strictly manage the science — they are there to manage expectations!
  - Keep a log of interactions with sponsor, pertinent CRO representatives, and FDA
  - Notes go a long way in the long term if they're organized!
- Consultants can help establish realistic timelines for a program with consideration to key stakeholders.
- Maintain program momentum
  - Significantly more challenging as we adjust to realities of COVID-19 response
  - Utilize virtual meetings as much as possible and be *flexible*

Build Your Network

- Understand what's happening in the field
  - Stay abreast of all major changes
  - Continue taking CE, read journals, stay up to date
- Build professional relationships
  - Your colleagues
  - Other consultants
  - BD reps and SDs at CROs you have consistently good experiences with
  - FDA reviewers

Best Practices of Communication: A Study Director's Perspective

Saurabh Vispute, PhD, DABT

Senior Scientist, Pfizer

Study Director

- 21CFR Part 58 Sub-part B

  The study director has overall responsibility for the **technical conduct** of the study, as well as for the **interpretation**, analysis, documentation and **reporting of results**, and represents the **single point of control**.

- Multifaceted job - requires wearing multiple hats and multi-tasking
  - Technical/Scientific
  - Compliance
  - Administrative
- Organizational and communication skills are key
  - Effective communicator - verbal, written, and listening communication skills.
  - Relationship building with key stakeholders - Sponsor, PIs, Consultants, Study personnel.
  - Delegate responsibilities to study support team - Trust is a key part of delegation.

Quality Conduct of Studies

- Pre-study planning
  - Discuss project details, expectations, and timelines
  - Coordinate resource scheduling with supporting functions and business lines
  - Discussion of potential veterinary intervention plan for anticipated effects
  - Protocol development and study set up with concerned teams
    - Refine study designs (3Rs) and recognize operational and logistical challenges
- In-life study conduct
  - Study oversight; Adherence to SOP and study protocol
  - Communication with study conduct personnel, especially in rapidly developing situations
  - Periodic in-life data review and study updates to stakeholders
  - Protocol amendment for changes
  - Record keeping - Study correspondence and documentation
    - Ensuring a written concurrent follow up of any verbal communications.

Quality Conduct of Studies

- Reporting
  - Meet timelines or adjust as needed with mutual agreement
  - Ensure contributing scientist reports are scheduled to meet main report timeline
  - Data review and report writing, consensus with interested parties on study conclusions
  - Study deviations, QA/QC of study data and reports, as applicable

A high quality study report is a reflection of quality and conduct of study

How to develop yourself as a Study Director?

- Be open to learning and enhancing new skills
  - Seeking an opportunity to cross train in another area of interest
- Achieving a balance to meet timelines and deliverables
  - Task prioritization and time-management is pivotal
- Honing technical writing skills for regulatory documents
  - Manuscripts vs study reports
- Recognize strengths and weaknesses and develop your own style
  - Be organized, calm, and confident. Maintain composure in high pressure situations
- Gain competency in problem solving and issue resolution
  - How you deliver bad news and mitigate when things go wrong – relationship building

Take Home Message

- Communication… Communication… Communication
  - Verbal – face-to-face, phone, meetings/conferences
  - Written – e-mails, study reports, presentations
- Leverage resources and expertise within your organization
  - Experience is valuable; someone may have encountered a similar issue before
  - Don’t hesitate to discuss with peers and seniors
- Learn, un-learn, and re-learn
  - Flexible; be open to adapting new processes, aligning expectations
  - Embrace operational differences across various labs
- Stay connected
  - Share experiences within and outside your organization
  - Maintain confidentiality