**Kick-Off Meeting Agenda:**

The purpose of this tool is to provide a sample Kick-Off Meeting Agenda. Conducting a Kick-Off Meeting for a new Sponsor and CRO engagement is a leading practice, especially for new engagements (whether tactical or part of a strategic partnership) that are for a clinical program, a clinical protocol/trial or a new functional or support service, (as part of a FSP model) (Document: RnR Tool 01- Sourcing Models and Oversight). As a leading practice, a Kick-Off Meeting should be conducted as a face-to-face meeting, if at all possible. Depending on the depth and breadth of content that should be covered, the Kick-Off Meeting could be a one-day or two-day meeting.

The proposed Agenda Topics and Presenters shown below should be revised and/or reordered to make the meeting fit-for-purpose for the engagement. In some cases, it is helpful to have a facilitator who is not assigned to directly work on the project/engagement. For some agenda topics, depending on the project or engagement, it may be helpful to address some topics in breakout sessions. For example, if it is a cross-functional engagement, then each function may hold a breakout session to address risks to functional area deliverables. As the meeting progresses, it should create the foundation for a Project Management Plan. During the meeting, it is important to capture all action items and identify owners and timing for completion. For additional topics that are raised that are not part of the established agenda, track these topics in a “parking lot” so follow up can occur after the meeting. Assign ownership and timing to parking lot topics. If the Kick-Off Meeting is a two-day meeting, then conclude day one with a social event for the team.

| **Time** | **Kick-Off Meeting Agenda Topic[[1]](#endnote-1)** | **Purpose** | **Presenter/s** | **Tools** |
| --- | --- | --- | --- | --- |
|  | **Introductions-** (include an Ice Breaker for new relationships) | Establish new relationships and engender trust | Facilitator |  |
|  | **Meeting Objectives-** (For clinical trials: include brief presentation on IMP, clinical development plan, protocol review, endpoints, etc. For FSP engagements: include presentation on organizational structure and how the function interfaces with other Sponsor functional areas and project teams.) | Establish, as a team, agreement on project /engagement objectives and expectations | Joint- Sponsor and CRO Senior Manager |  |
|  | **Project/Engagement Business Assumptions**- review key elements of contract scope of work | Share scope of the engagement and basis for contract assumptions used | Facilitator | Process Tool 01a- Task Ownership Matrix |
|  | **Project/Engagement Technical Assumptions**- review key elements of the project or engagement (e.g. countries for engagement, other third-party providers used, SOPs followed, tools/templates used, etc.) | Share and discuss execution related assumptions | Joint- Sponsor and CRO Project Leads | Comm Tool 20 - Master Class Setting Expectations Worksheet |
|  | **Project/Engagement Quality Assumptions**- review definitions for quality | Gain agreement of quality expectations | Facilitator | Avoca Quality Agreement Template |
|  | **Create/Confirm Milestones**- Define key deliverables and delivery dates | Gain agreement on key deliverables and delivery dates, including interdependencies and prerequisite activities | Joint- Sponsor and CRO Project Leads | Tech Tool 02- Project Management Oversight |
|  | **Roles and Responsibilities-** RACI Charting for each deliverable | Gain agreement on key accountabilities and responsibilities; clarify when Sponsor should be consulted or should provide approval vs. being informed; avoid micromanagement by Sponsor | Facilitator or CRO Project Lead | Roles and Responsibilities Guideline, RnR Tool 04- Using RACI Charting and Analysis, RnR Tool 06- Template RACI Chart |
|  | **Risk Identification-** Review potential risks to quality and timely delivery of milestones and key deliverables. (If a cross- functional engagement, involve all functions.) | Proactive planning to understand challenges | CRO Project Lead and Deliverable Owners | Risk Tool 01- Elements of Risk Management, Risk Tool 07- Risk Management Plan Template |
|  | **Confirm/Categorize Risks**- assign probability (high, medium, low), assign impact severity/criticality (high, medium, low) | Proactive planning to prioritize risk management | CRO Project Lead and Deliverable Owners | Risk Tool 05- Provider Risk Assessment and Mitigation |
|  | **Develop Mitigation Plans/Contingency Plans**- Focus on high probability, high impact risks. Discuss metrics and detectability, establish mitigation plans, and consider the costs and benefits of implementing mitigation plans. Assign ownership and target completion dates for mitigation activities. Define contingency plans with triggering thresholds. Assign ownership and target completion dates for contingency actions. | Proactive planning allows rapid response to indications that a risk is being realized. | CRO Project Lead and Deliverable Owners | Risk Tool 06a- Risk Prevention and Detection Controls, Risk Tool 07a- Risk Oversight Table |
|  | **Metrics and Status Reporting-** Milestone Tracking, KPIs, KQIs, KRIs, etc. Determine form, frequency and ownership | Establishes focus on milestones | Facilitator or CRO Project Lead | Metrics/Analytics/Technology Guideline; Comm Tool 21 - Project Status Report |
|  | **Third-Party Provider Presentations-** Review key procedures (lab data, ECG testing, etc.), data flow, key contacts and expectations | Establishes clarity for all the parties involved | Facilitator and Third-Party Provider Representatives | Process Tool 05c- Project Provider Tracking Table |
|  | **Communication Planning/Meetings-** Define communication mechanisms (email, meetings), frequency, approach (teleconference, face-to-face, etc.), purpose, required vs. ad hoc attendees, roles and responsibilities for agendas and meeting minutes, timing for submission of meeting minutes, expectations for email response times, back-up support, managing vacation calendars, team membership, contact information tracking, central document repository, etc. | Establishes clarity of expectations and ensures rapid, appropriate communication; avoids micromanagement | Joint- Sponsor and CRO Project Leads | Comm Tool 01- Communication Matrix template, Comm Tool 02- Communication Management Plan |
|  | **Issue Escalation Process-** Establish how issues will be managed, communicated, tracked, etc. | Ensures appropriate escalation, timely resolution and avoid micromanagement |  | Comm Tool 03- Issue Escalation template, Comm Tool 04- Escalation Pathways |
|  | **Training Requirements**- Define list of role-based training requirements for data systems, SOPs, therapeutic area/indication, protocol, issue escalation and resolution, etc. with expectations for timing, testing, documentation of completion, refresher training, new hire training, training oversight | Establishes foundation for quality delivery | Joint- Sponsor and CRO Project Leads | Process Tool 03a- Process Tracking Table |
|  | **Review of Action Items and Parking Lot Topics**- ensure all action items have an owner assigned, target date for completion and mechanism for communicating completion | Tie up loose ends and ensure complete follow up after the meeting | Facilitator | Comm Tool 12- Action Item Template |

1. Derived from Charles, Owen; “Setting the Groundwork for a Successful Outsourced Clinical Trial: The Use of a Kick-Off Meeting and Project Management Charter for Managing the Sponsor/CRO Relationship; American Pharmaceutical Outsourcing; March/April 2006

   For questions or additional information, please visit <http://theavocagroup.com/contact/>. [↑](#endnote-ref-1)