Biotechnology Clinical Trials Outsourcing

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DRUG INFORMATION ASSOCIATION

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Session 1

A Risk Management Approach for the Development of an Outsourcing Strategy

Case Study

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Session Leaders

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Heidi Egelhoff, UBC, Clinical Technologies Group

Stewart Hallett, Medivation

Steve Nelson, FibroGen

Overview

- Theme: What to outsource?
- Context
  - Early clinical phase
  - Mandate given to Clinical Operations
- Challenges:
  - Time and budget
  - New Therapeutic Area

Goals

- Steps needed to develop core competencies
- How to decide what to outsource and what to keep internal?
- What elements are needed to decide what SOPs will be used?
- What information is needed to assess risks?

Logistics

- Divide audience in sub-groups
- All tables to read page 3 of packet (description of scenario and mandate)
- Each sub-group is assigned a facilitator from the panel
- Identify a group spokesperson and note taker
- Use flip-chart to document main take home messages

Session 1

A Risk Management Approach for the Development of an Outsourcing Strategy

A Case Study Exercise

Session Overview:
Clinical development plans and the outsourcing strategy needed to implement them require a careful risk management approach. Make or buy decisions should be made early and re-visited periodically based on milestones reached and growth rate. Small biotech companies face a unique challenge in regards to resource availability and the maturity level of their infrastructure. They also tend to struggle with reaching the right balance between keeping tight control over study activities while transferring responsibilities to a service provider. This session will take the form of an interactive case study. We will discuss how to identify and develop core competencies, how to determine functions that are better to outsource, how to make decision about whose processes to follow, how to assess and mitigate risk and how to adapt the outsourcing strategy to manage the growth of the organization.

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Time for the Case Study:
8:30 – 10:00 am
Session length: 1½ hours (90 minutes)

Instructions to participants	5 minutes	8:30 – 8:40 am
Participants work in small groups	40 minutes	8:40 – 9:20 am

Address the tasks listed below:

- Identify a group spokesperson(s)
- List major points on flip-chart
- Prepare brief presentation for group discussion

Discussion by small groups and panelists	40 minutes	9:20 – 10:00 am

Breakout Groups (sub-teams 1 to 3, as needed)

The breakout groups will be arranged at the time of the seminar based on number and distribution of participants/

Sub-Group 1: instructions will be given at the workshop

Sub-Group 2: instructions will be given at the workshop

Sub-Group 3: instructions will be given at the workshop

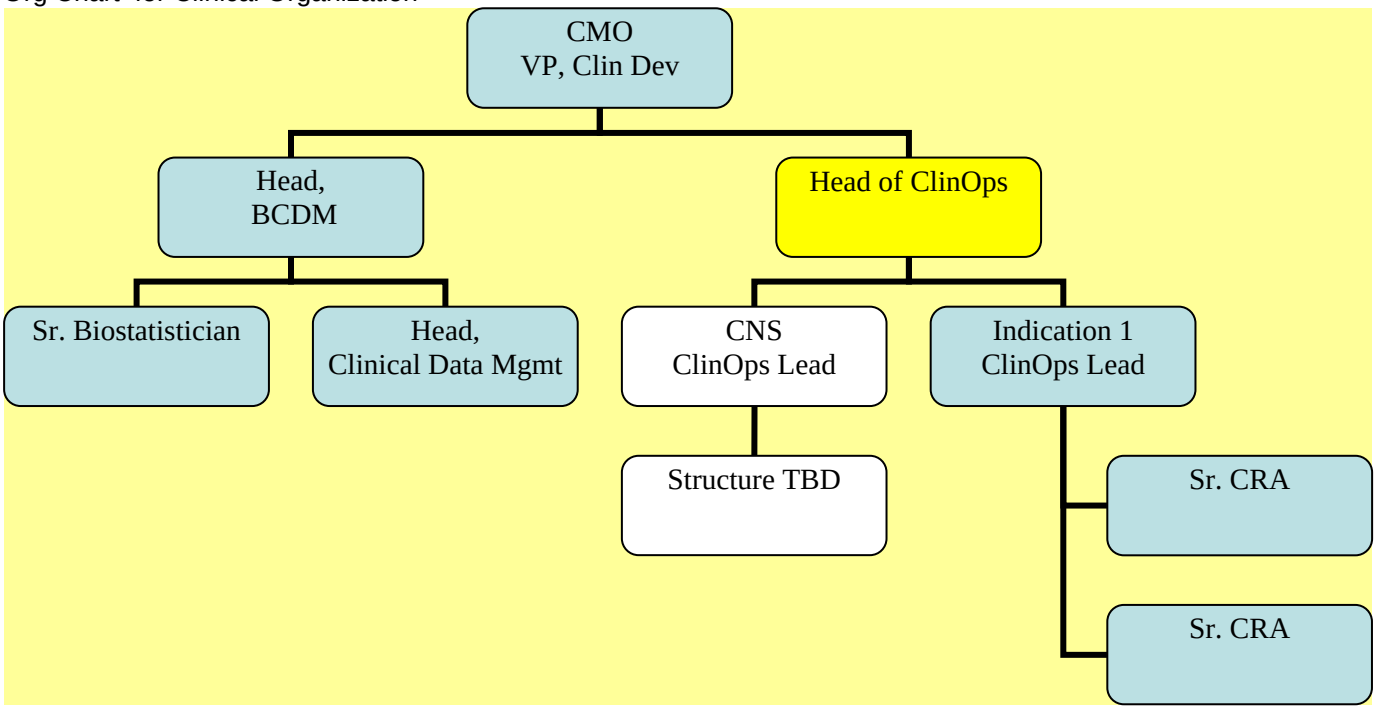
Case study scenario:

Your company, Biothèque, Inc., is about to enter into the clinical phase of the drug development process. A new, first in class, compound, Bio-3-20 is your main clinical candidate. The IND is being drafted and should be ready for filing with the FDA in 3-5 months. The indication that you are targeting is a bipolar disorder. CNS is a new Therapeutic Area (TA) for your company.

You are playing a leadership role in the Clinical Operations group. You have been given the mandate by the CEO and the CMO/VP of Clinical Development to do the following:

1. build an optimized budget and timeline leveraging some functional resources internally
2. provide a staff assessment of internal staff and provide 1-2 scenarios to outsource the work efficiently and effectively
3. develop the department infrastructure and hire/train adequate resources / plan to hire consultants during gap periods
4. develop internal expertise in the new TA by tapping into Key Opinion Leaders (KOL) and expert statisticians familiar with the TA
5. leverage some of the processes in place from the other TA / review and revise SOPs as necessary
6. develop a straight forward internal resourcing and outsourcing plan
7. develop a list of core competencies for your department
    a. What will you develop in-house?
    b. What will you routinely outsource?
    c. What are you going to outsource to bridge a temporary gap?

Org Chart for Clinical Organization



Note: There is no internal database in the company

In indication No 1, there are 2 CRAs reporting to the ClinOps Lead and they are using a few CROs in a functional outsourcing model (which means that different CROs are responsible for monitoring, data management, IVRS, drug safety, etc.)

Sub-Team No 1

List of questions

What are your priorities for filling some of the open headcounts?
How would you decide between project headcount vs. functional headcount?
What will be your hiring strategy?
How do you plan to train new employees?

Time permitting, start addressing list of mandate from the CMO (points 1 to 7 on previous page)

Sub-Team No 2

Participants to discuss what will routinely be outsourced and what will be kept in-house. Use list below and feel free to break down even more or add categories

Roles and Responsibilities:

Services	Biotech	CRO
Protocol Development		
Project Management Activities		
Startup Activities		
Monitoring Activities		
Pharmacovigilance		
Medical Monitoring		
Database Set-up		
Data Management		
Site Close-out Activities		
Statistical Analysis Plan		
Statistical Analysis		
Medical Writing		

- What are the main elements of a Clinical Development Plan?

  You will have the opportunity to work with an internal Project Manager for this project. However, you are responsible for the clinical trial planning.

- Discuss how you would execute other upcoming studies. (e.g. would you want to use the same CRO in the future?

- How you planning to bring in more activities in-house? Why? What are the pros and cons to use the same CRO?)

- Complete the top 5 issues that may come up.

Sub-Team No 3

- From the moment you have decided that you need to outsource, what are your first steps to identify a CRO partner?

- Write a list of 5 to 10 steps and a high level timeline for the next 6 months. The end result will be to have an RFP finalized and 3 or 4 CROs selected to receive the RFP.

- What kind of due diligence do you need to do? In other words, what are your obligations or what kind of activities do you feel you must undertake to assess the experience and capabilities of the CRO?

- Discuss the SOP situation: once you have identified a CRO, how do you decide what SOPs to use? If you use a mix of SOPs, list an example of a breakdown (sponsor SOPs vs. CRO SOPs)

Time permitting:

- CRO Management Plan: list the elements of such a plan that would help you mitigate risks.

Time Permitting (give this part to a table who has completed other assigned tasks)

Risk Assessment Template.

Discuss typical risks/issues associated with the initiation of a relationship with a CRO

Use model below.

#	Risk Description	Affected Area/s	*Probability Of Occurrence	*Impact to Project	Priority	Strategies/Actions (Avoidance, Transference, Mitigation, Acceptance)	Owner

Questions for Breakout Sub-Groups

Instructions:

- Answer the questions assigned to your working group
- Identify the issue and identify why this issue poses a challenge (i.e. identify the gaps)
- Offer a solution for each question
- Select a note taker who will take note and capture the group's output on the flipchart
- Select a speaker who will present your responses and finding to the group at large