



## Vendor Management<sup>+</sup> and Oversight

Aligning all of your vendors to work together towards your objective

## Excelya x Vendor Management<sup>+</sup> & Oversight (ExVMO)

- What is ExVMO?
- ExVMO benefits
- How to request central service oversight?
- How to work with ExVMO contributors?

# WHAT IS ExVMO?



# Your Vendor Challenges

Significant ramifications for costs, quality and timelines

## Increased complexity

To successfully deliver life-saving therapies you need expert vendors, from patient safety to regulatory scrutiny. But calling on these vendors decreases oversight while increasing risk and costs.

## Finding simplicity

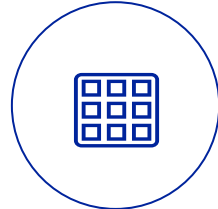
We ensure all your vendors are working together towards your objective by providing the right mechanisms for accountability. Quality is ensured, data is consistent, costs are decreased, delivery is on-time.

# What is ExVMO?

- Our comprehensive central services solution aligns all of your vendors to work together towards your objective. Our ExVMO Contributors find simplicity within complexity.
- A functional and organizational “**Deliverables**” model implemented in Trial Operations called **Vendor Management and Oversight**.
- A model with dedicated specialized Contributors for each centralized activity of the study covered by ExVMO. These activities are:
  - Central Laboratory Services (CLS)
  - Bioanalytical and Local Labs
  - IRT
  - COA and eCOA
  - Home health services / Home nursing
  - Central Reading (imaging)
  - Cardiac Safety
  - Respiratory
  - Actigraphy
  - eConsent

# Features of our ExVMO Contributors

#01



**Cross-disciplinary**  
Have cross-disciplinary view across multiple therapeutic areas and are part of the Study team

#02



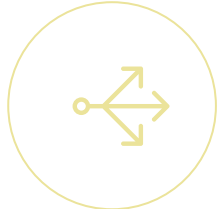
**Specialized**  
Service experts specialized in managing their activities across studies

#03



**Flexible**  
Flexible working patterns to cover multiple time zones

#04



**Coverage**  
Are typically involved in several studies

#05



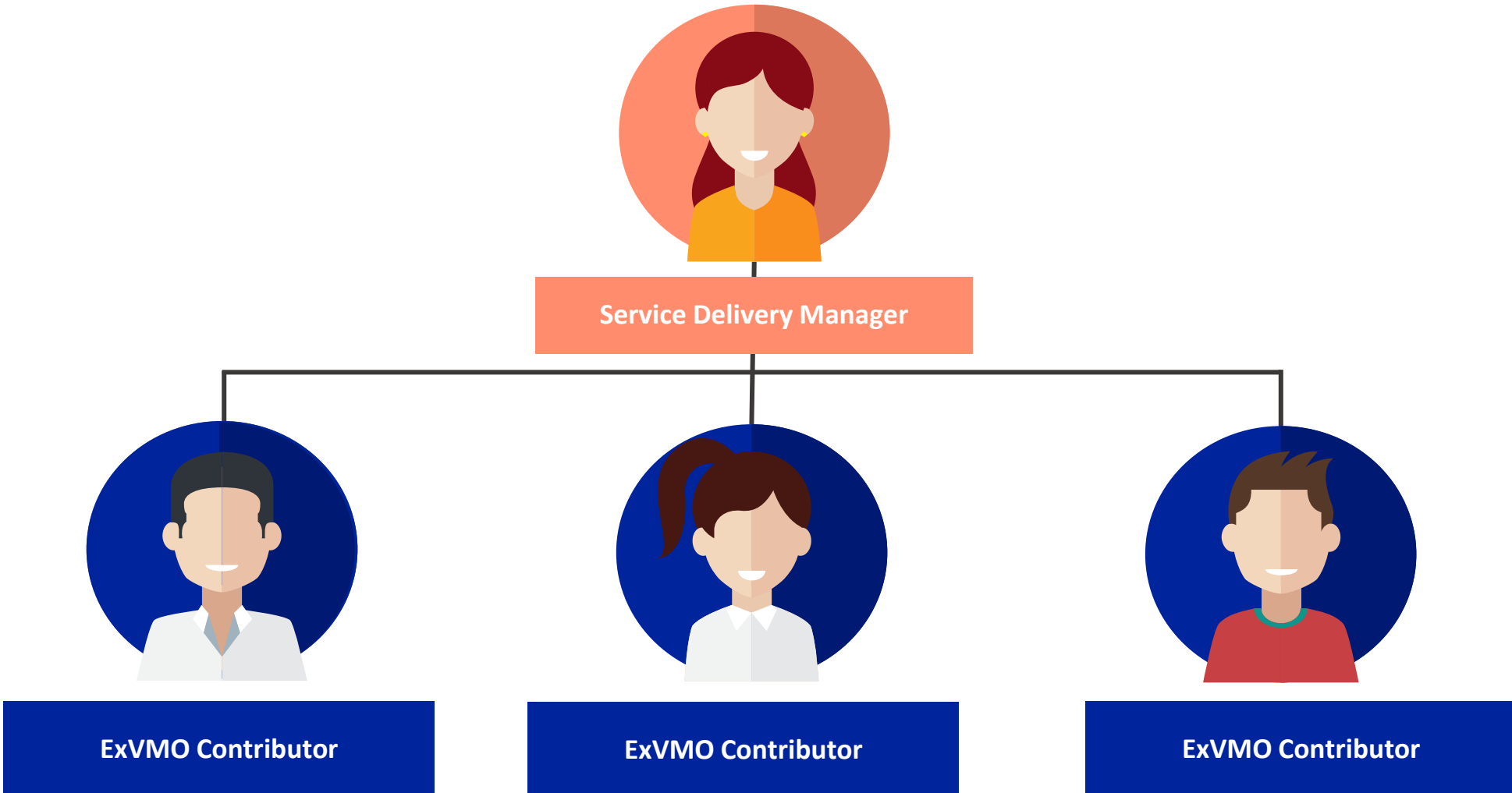
**Task-oriented**  
Work based on a specific list of tasks which defines their scope

#06



**Excelyates**  
Are Excelya employees and we will indemnify clients against co-employment risk

# How we organize our team



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# Service Delivery Managers

ExVMO Contributors are mentored and supervised by their Company Manager called

## Service Delivery Manager (SDM) who guarantees

01

### Quality

All outputs meet client and Excelya quality standards.

02

### Expertise

Real level of expertise of the contributors

03

### Continuity

Allocation of emergency backup ExVMO Contributors when absent

04

### Contact

The SDM works closely with the designated Client contact to provide seamless services.



#### Profile of Study Delivery Manager

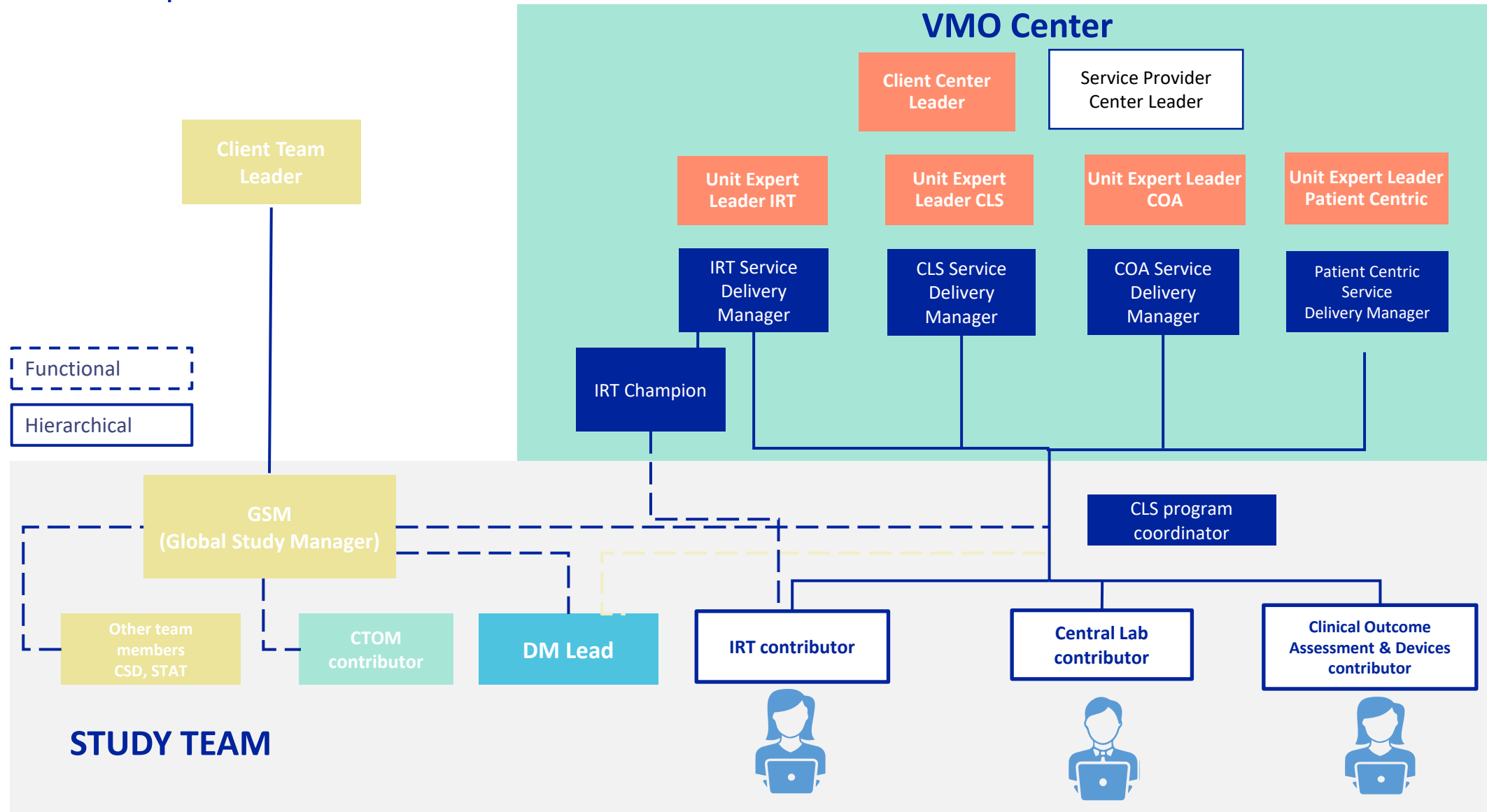
- Typically, 5+ years experience in clinical trials with CROs
- Project Leaders who understand data flows
- Management experience

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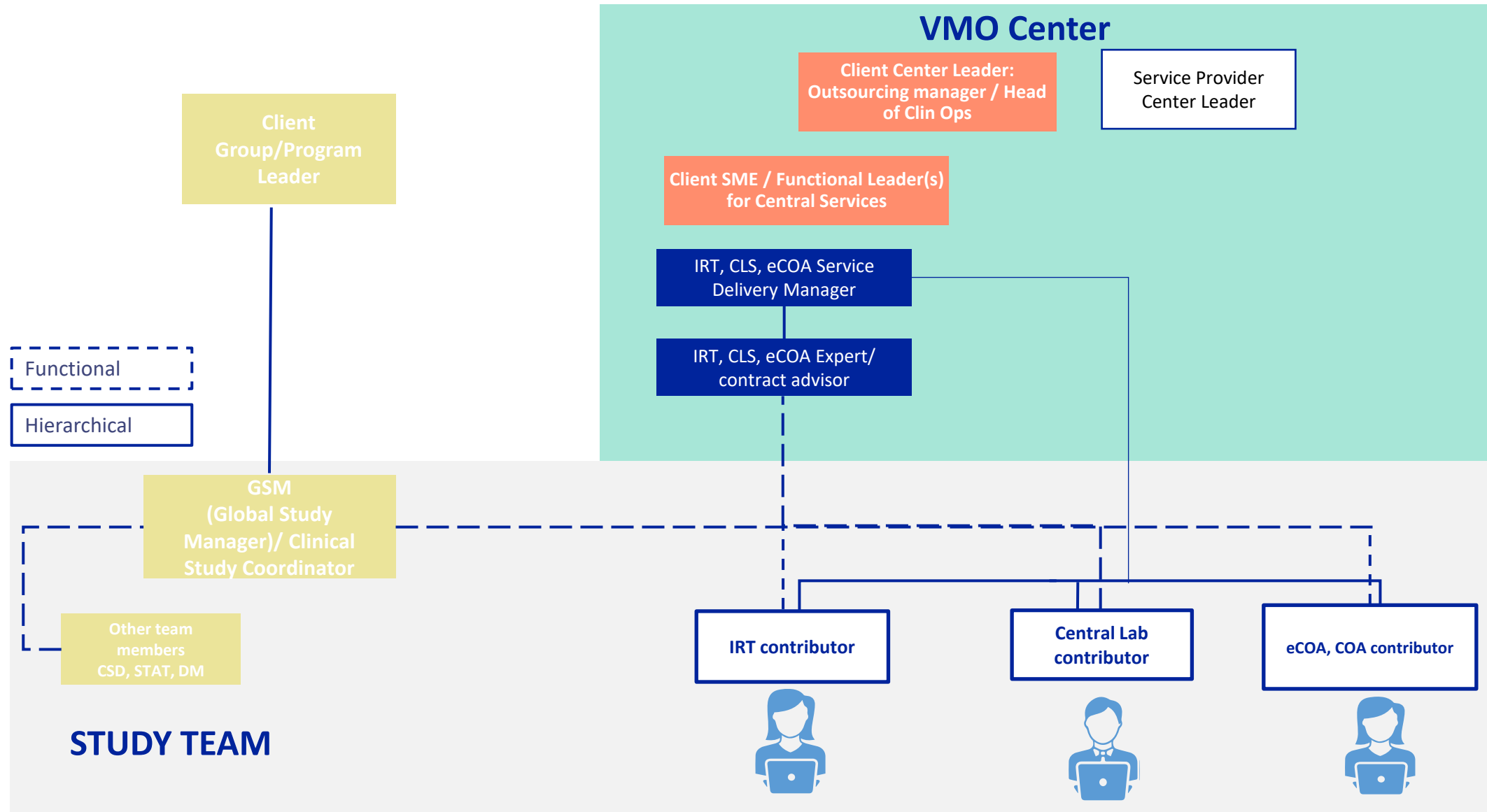
# Organization: Case Study #1

## Interaction with Top 10 Pharma



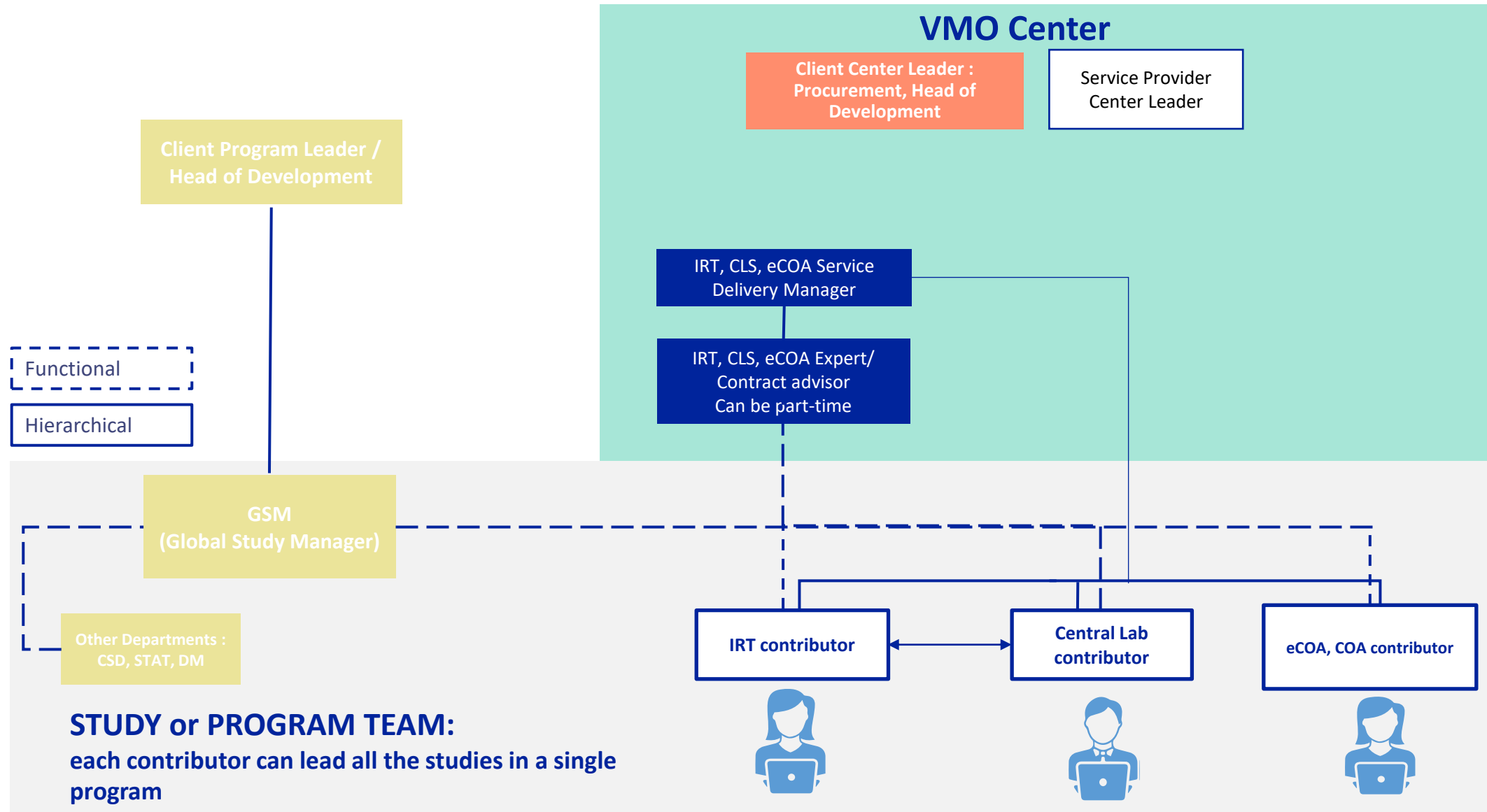
# Organization: Case Study #2

## Interaction with mid-size Pharma



# Organization: Case Study #3

## Interaction with Biotech



# ExVMO BENEFITS



# Improved quality, costs and time

## 1 Ensured quality

Contributors are experts, **capitalizing on knowledge, experience and training.**

Contributors **master all tasks and integrate all changing standards** (processes/ organization/ tools).

GSMs have a **greater Project Management role** and to develop **more strategic vision.**

## 2 Decreased costs

Cost reduced with **gain in expertise, optimized processes.**

**Activities delegated** that are reproducible and require level of expertise or technical skills.

GSMs free to be **more efficient in the study oversight.**

## 3 Gained time

Contributors are **fully operational** for each study in a short time.

**Contributors take over overlapping complex activities at study start-up** to alleviate significant burden to GSM.

**Synergies created** cross therapeutical areas for the same tasks or within study programs.

# By the numbers: Case Study #1



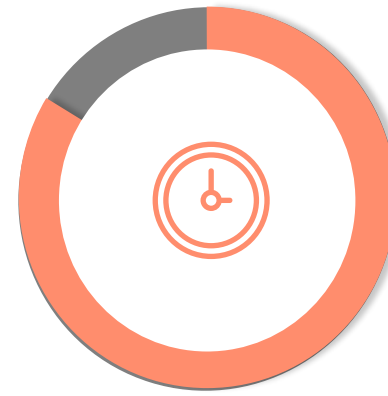
## Decreased costs by 16%



We assessed all vendors and scope of work to harmonize resources and reduce study costs by 16%.



## Optimized time by 10%, twice



In the first 18 months, we optimized time spent by 10%. Another 18 months later, we had optimized by another 10%.

# Support for our Contributors

Each Contributor receives support of any of these types:

## Adviser

Study Champion or mentor provides study level QC or mentoring action during activity setup.

## Expert

Interacts with client Experts for their activity and with the contributors to provide technical and operational expertise in their activity.

## Coordinator

Coordinator acts at the program level to harmonize practices, timelines and search efficiencies.

# WORKING WITH OUR ExVMO CONTRIBUTORS





# Adding value at every step

## Completion of RFPs

Step One



Although ExVMO Contributors can join a study at any time, we highly recommend involving the ExVMO contributor at the study KOM, i.e. when RFPs are completed and ready to be sent to the vendors

Contributors work with the study team, vendor and buyer to help clarify protocol-related questions. One objective: to produce a final proposal and budget within reduced timelines.

Step Two

During RFP Process

## Vendor Kick-Off Meeting

Step Three



Before the Kick-Off Meeting, due to workload management, the assigned contributor could hand over his activity to another contributor, who will stay for the entire setup and follow-up stages

# Adding value at every step

## Setup

Step Four

The Contributor translates protocol requirements into the system, manages user access, tests the system, ensures delivery of equipment or material before FPS. Typically performed by one contributor with no switch of resource.

## Follow-Up / Recruitment

Step Five

During the Follow-Up / Recruitment Phase, the Contributor follows deliveries throughout site initiations, routine FU tasks, tackles issues, performs system amendments.

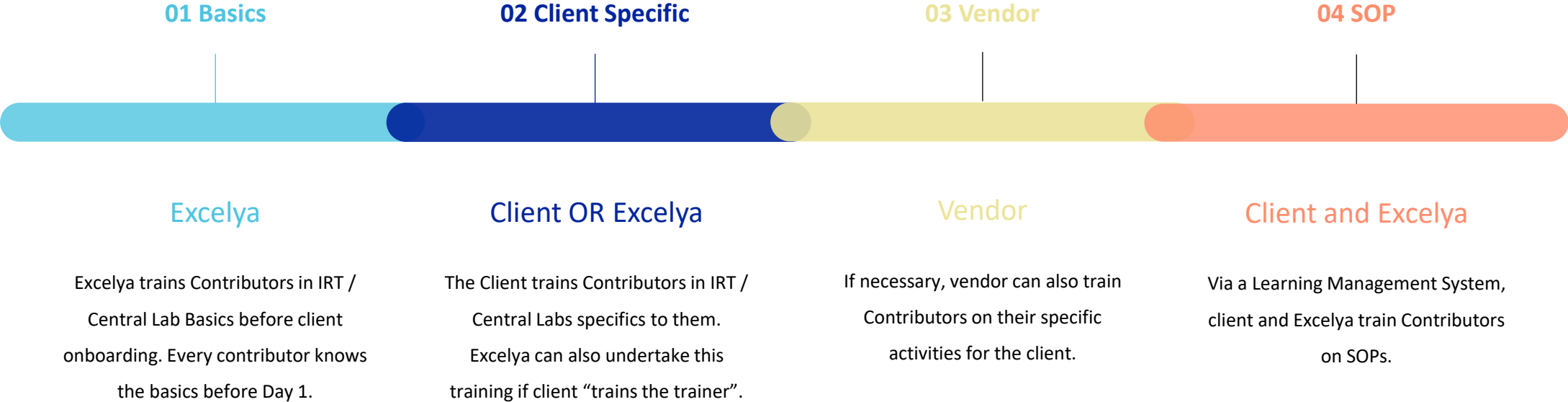
## Study Completion

Finish

The Contributor reconciles budgets, collects data, issues TMF reconciliation, lists lessons learned.

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# Training the best team: IRT / Central Labs example



# Tools we leverage

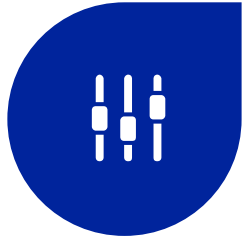
#01



## Sharepoint

Generic or Study  
Sharepoint.  
Contributors may use  
Client's and Excelya's  
Sharepoint

#02



## Trackers

Contributors may  
build activity trackers  
(budget, ...) or use  
vendor user trackers

#03



## Time Sheets

Time spent by  
contributors between  
milestones is recorded  
and analysed

#04



## Databases

Contributors contribute  
to Data reconciliation

#05



## CTMS Reporting

Contributors may be  
given access to CTMS  
reporting tool

#06



## GANTT Planning

Contributors may be  
given access to study  
planning tools

# How we work

## Meetings

The Contributor participates in regular and ad hoc meetings with the Study Team, as necessary and agreed upon with the Client.

## Reporting

Monthly reports sent to the Study Manager as per established reporting calendar.



## Positioning

Contributors are part of the Study Team with defined and limited responsibilities. Backup contributors are available and cover for each other for emergencies only.

## Communications

Contributors escalate issues according to Communications Plan.

## Budgeting

Change Orders are always validated by Global Study Manager.

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THANK YOU

ANNEX



# Describing our scope: Case Study

Interaction with Top 10 Pharma

