

Clinical trial Initiation and site start up

Site and Investigator Selection



Module 6 Topic 1_1

Site Start Up

Successful study start-up is an essential first step, and relies on overcoming a range of factors.

These include:

- Country and site selection
- Streamlining and
- Proactive planning, and patient recruitment strategy

These steps can also be expressed as setting the right path, getting off to the right start, and finding the right patients.



Roadmap

- Introduction
- Sites
 - How to identify?
 - Criteria for a good Site
- Investigators
 - Who are they?
 - What to look for?



Sites

- More than 60% of sites report increasing difficulty in conducting clinical trials:
 - Poor recruitment
 - Contract & budget negotiation & finalization
 - Protocol complexities
 - CTA Agreement



Sites

- Which site to identify?
- When to identify?
- How to identify?
- Where to look for Sites?

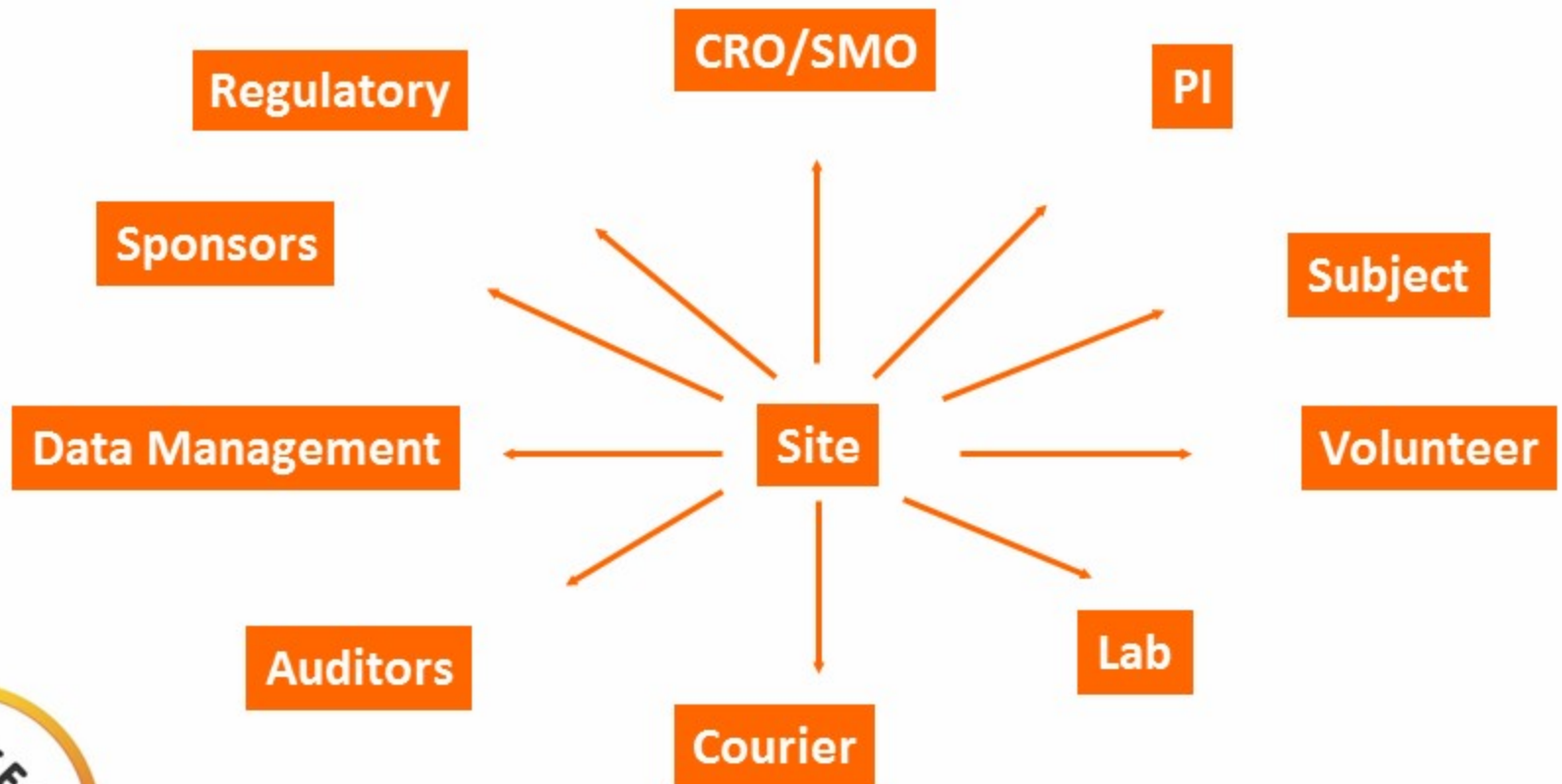


Site - Expectations

- Good trial
- Good Sponsor
- Ethical & Scientific research
- Ensure protection of rights, well being and safety of all study subjects
- Conducive to partner with multiple players/ organizations



Multiple Players at site



Sponsors - Expectations

- Adequate infrastructure
- Trained, motivated & experienced research staff
- Professionalism, integrity & Trustworthy
- Progressive & compatible management
- Organized



Site

- Which can qualify as the Site?
- Hospitals – Govt. or Pvt.
- Nursing Homes
- Registered Institutional Ethics Committee is a must
- Should have facilities to undertake emergency(ies) as required



Site - Criteria To Look For

- Location
- Specialty
- PI and Team
- IRB
- Lab support
- Other Equipments
- Commercials
- Space



Site - Criteria To Look For

- Time of staff
- Enrollment timelines
- Target enrollment
- Quick off the block
 - Timeline for:
 - IRB Submission to Approval
 - Contract agreement
 - SIV to FPFV
 - Enrollment per week/month



Site - Sponsors Criterion

- % age of protocol violations
- Constancy of manpower
- JD of manpower
- SOP
- Turn Around Time for Data clarification
- Monitoring & Audit Reports
- Quality of data



Feasibility

A good feasibility survey must be undertaken at an early stage in the selection process to ensure that a study can be conducted in the country or at the site of choice.



Pre-Study Site Visit (PSSV)

- One visit MUST be on-site prior to study initiation
- Outcome decides site's participation
- Conducted by CRA/PM
- Lasts minimum of 2-4 hours



PI Identification

- Qualification
- Experience
- Training



PI Identification

- Qualification
 - MBBS
 - MD/MS
 - DM/Mch
 - BDS/MDS
- Training
 - ICH GCP
 - Specific
- Experience
 - Clinical
 - Clinical Trial
 - Specific Indication Area



PI Identification

- Who Does it?
 - CRA/CRC/PM
 - Database
 - Sales Dept.
 - Marketing Dept.
 - Cross Reference



PI Identification

- Sponsor PM:
 - “Sir, we have a clinical trial for newly diagnosed Ca - Pancreas. Could you please tell us how many patients can you give us in 6 months?”
- Dr. Mahesh, HOD, Oncology, ABM Hospital:
 - ‘Oh! I can give at least 25 patients. When are you planning to start the trial? Where is the PI meeting?’



PI Identification

- The single most important activity
- Experience
- Inclination, interest, initiative
- Team - motivated, ability to motivate
- Drive
- Commitment
- Respect timelines



PI Identification

- Qualification - CV review
- Experience
 - Therapeutic Interest Area
 - Clinical Trial
- Subject Load
- Professionalism, Interest & Time
- Support Staff

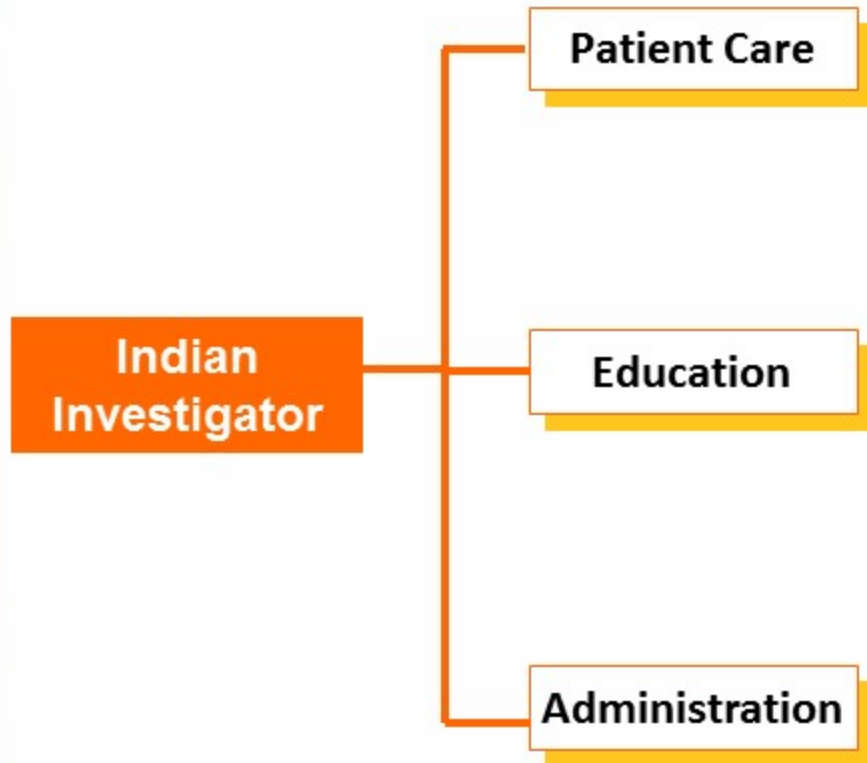


PI Identification

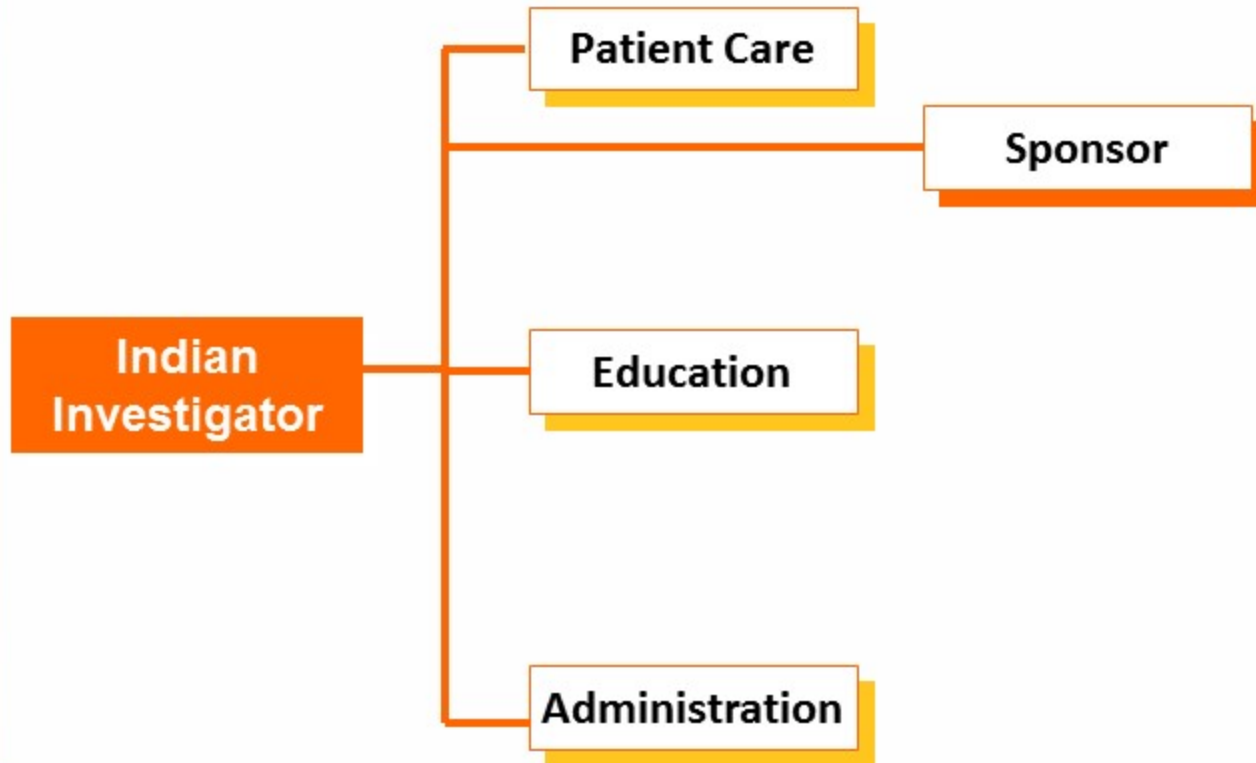
- Brand Names must be included
 - Name
 - Driving force
 - Opinion Leaders
 - Prestige
 - Years of experience



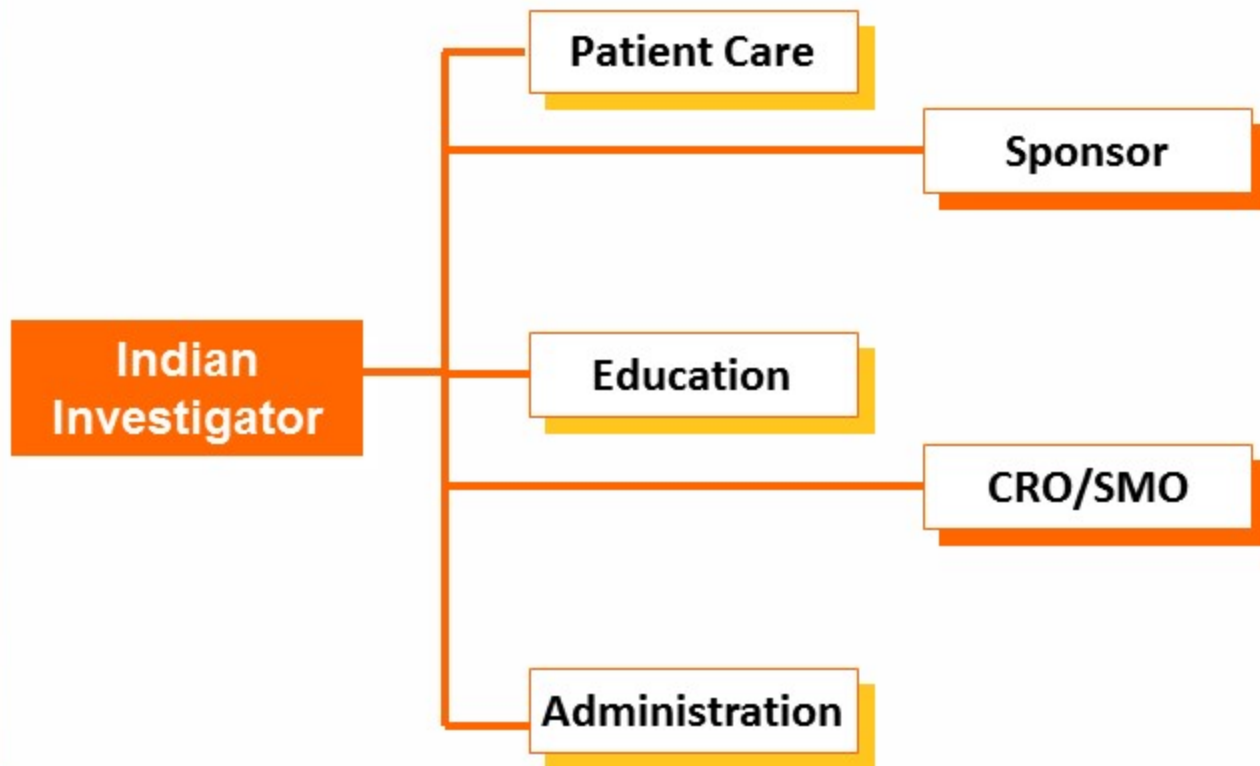
Indian Investigator



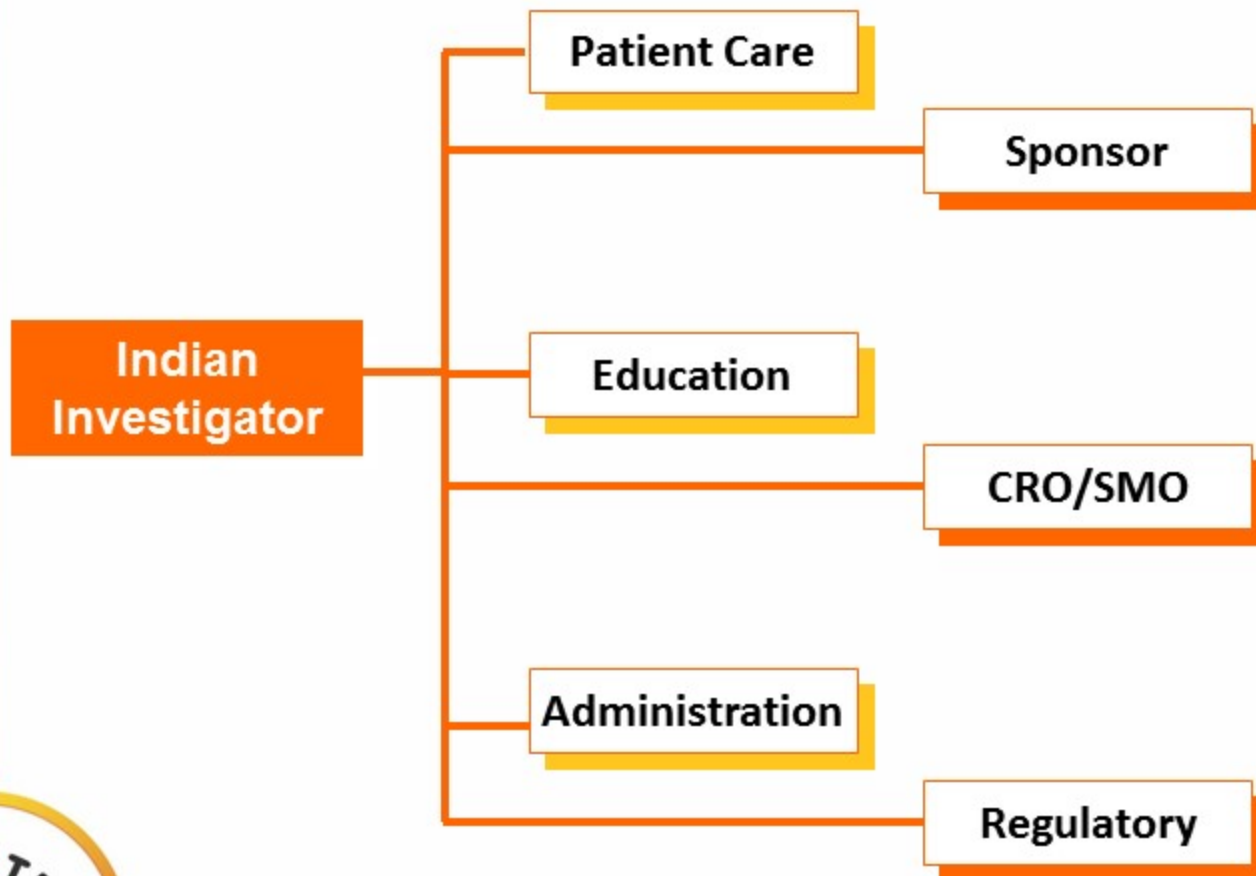
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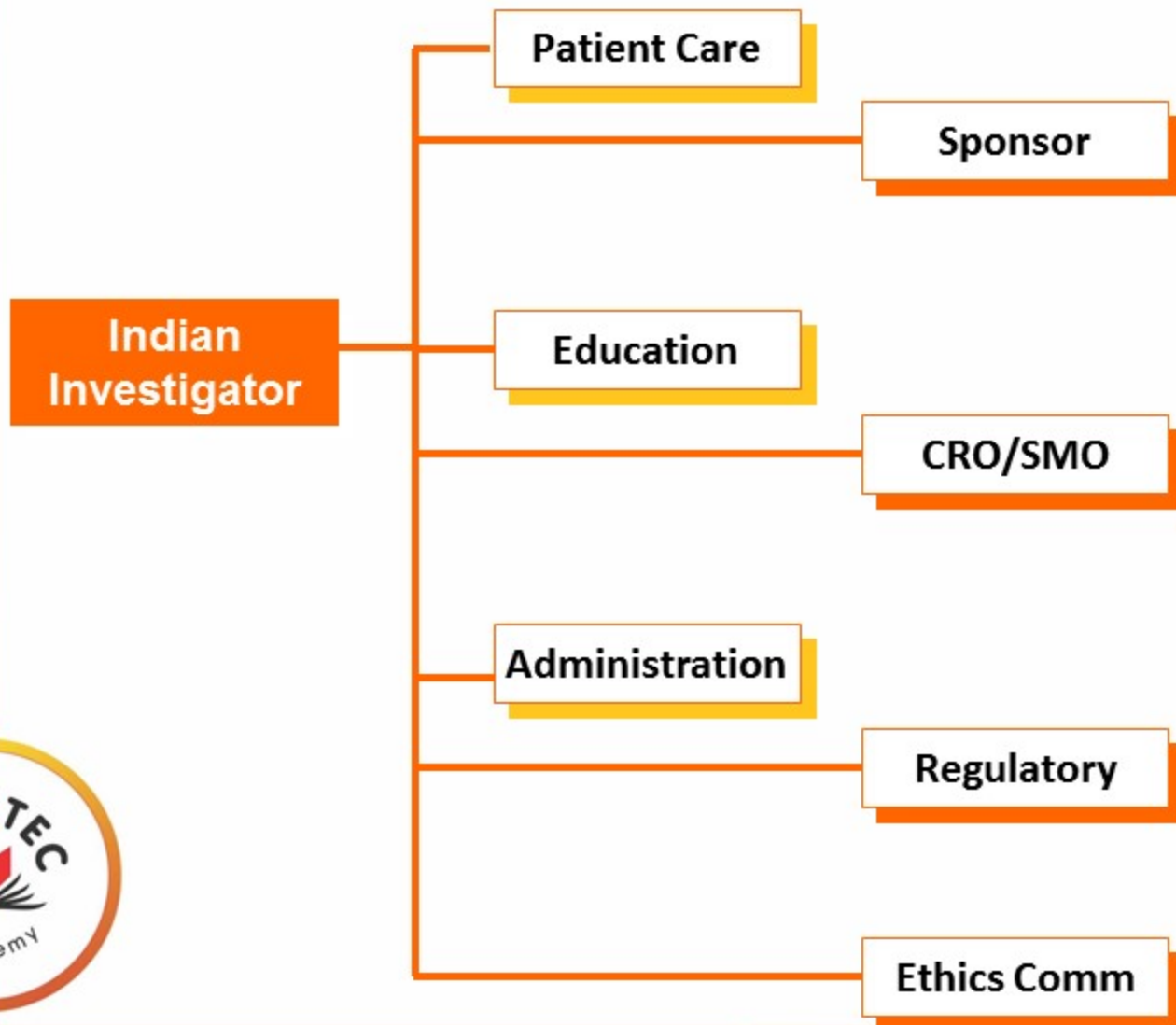
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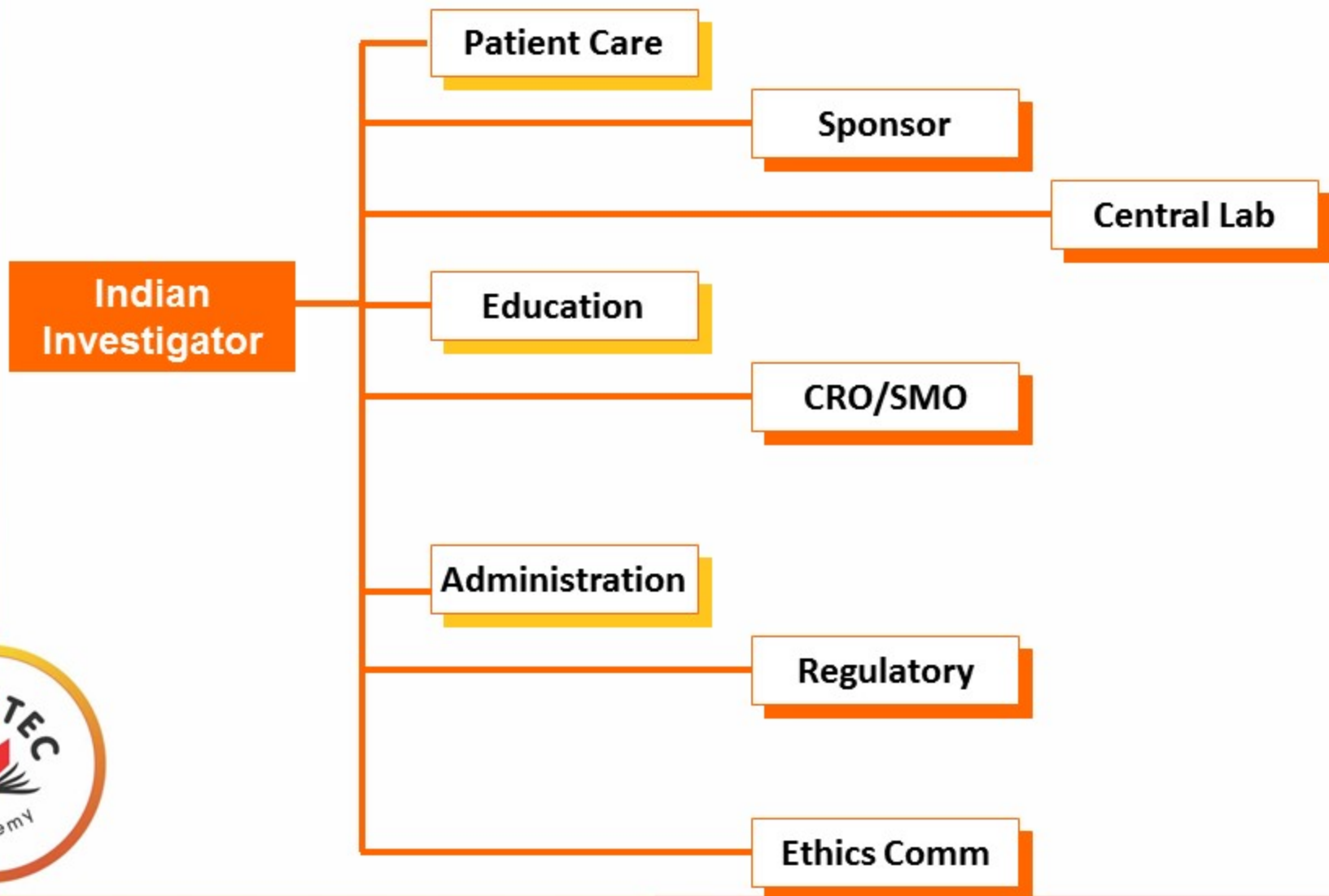
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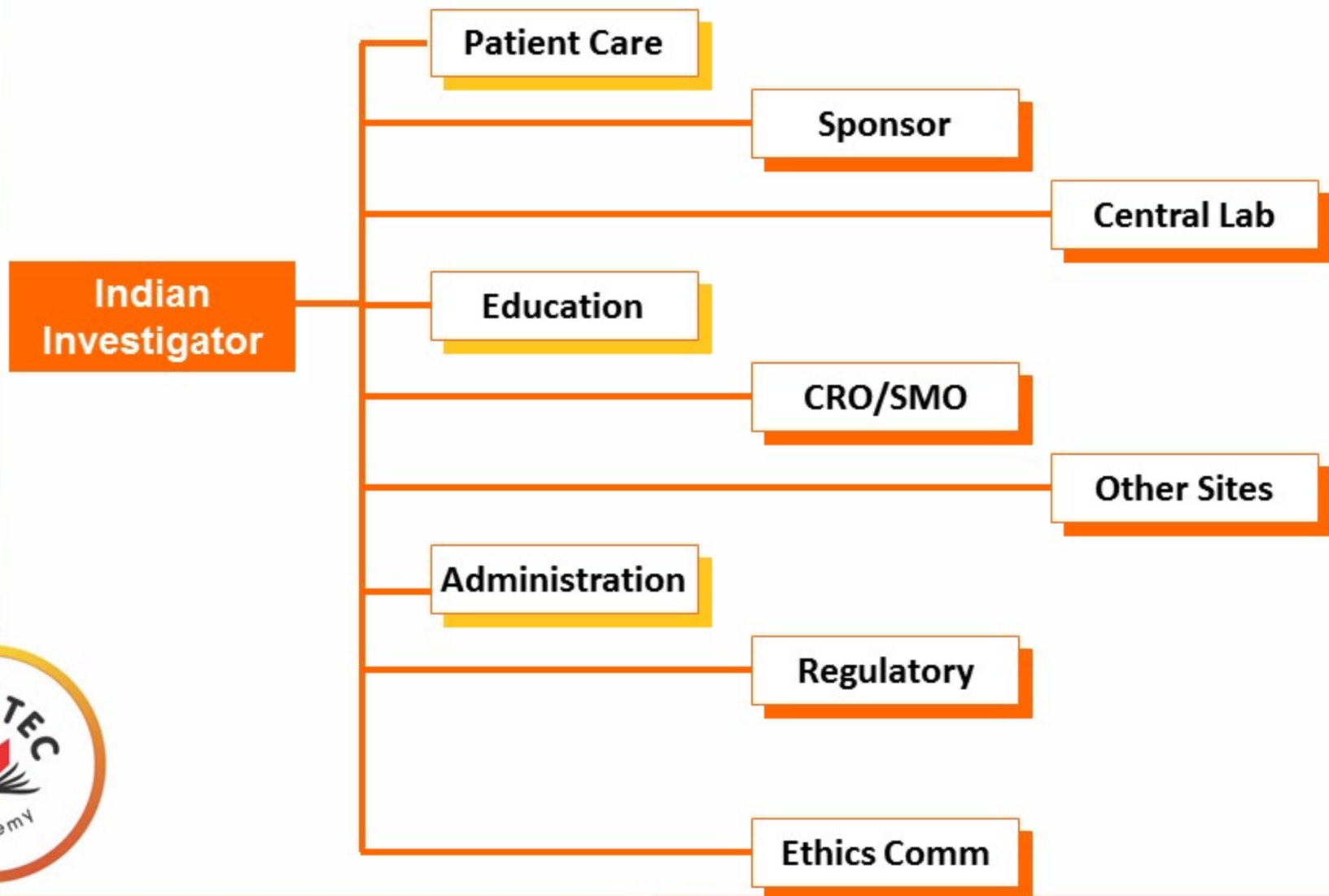
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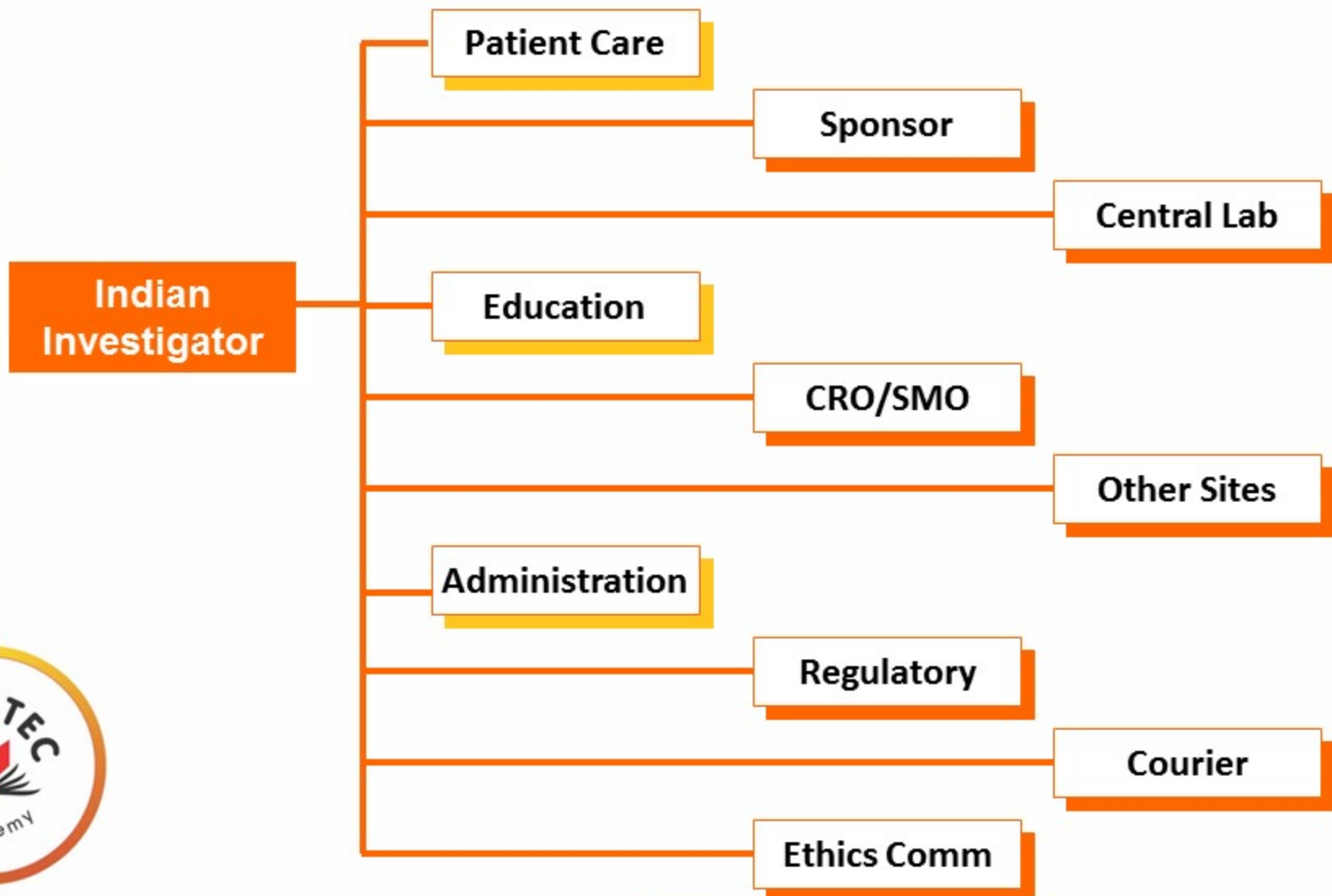
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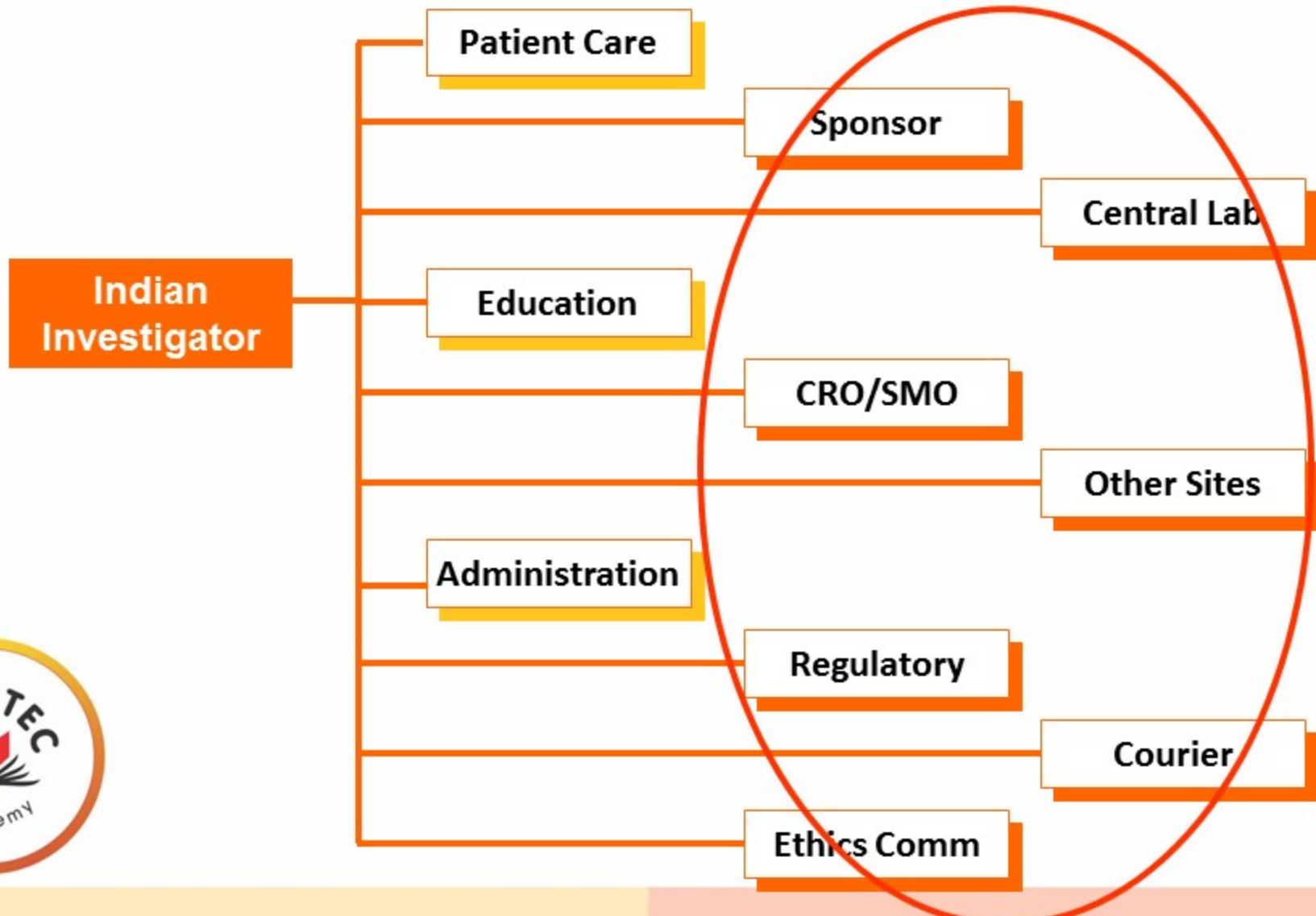
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Indian Investigator



Indian Investigator



A Typical Selection Process

Sponsor/CRO

Feasibility



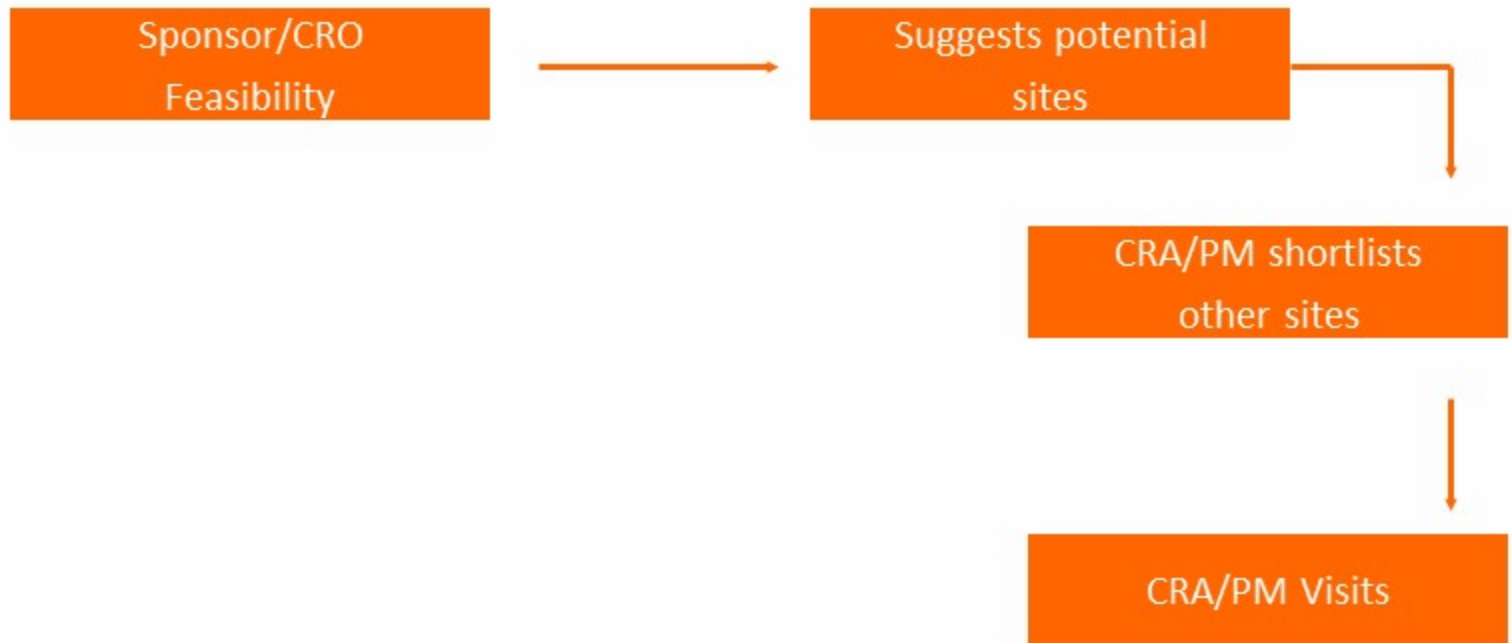
A Typical Selection Process



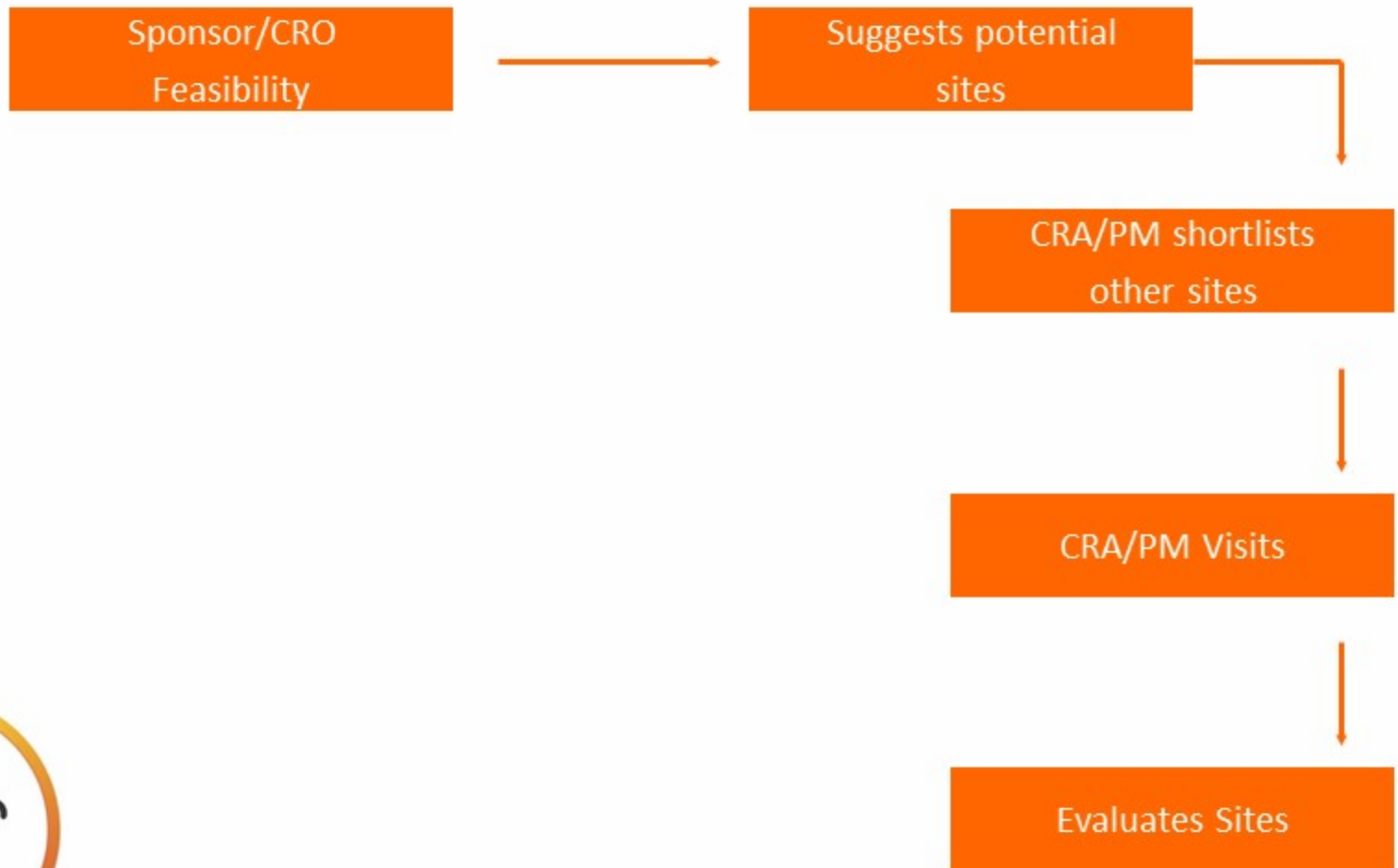
A Typical Selection Process



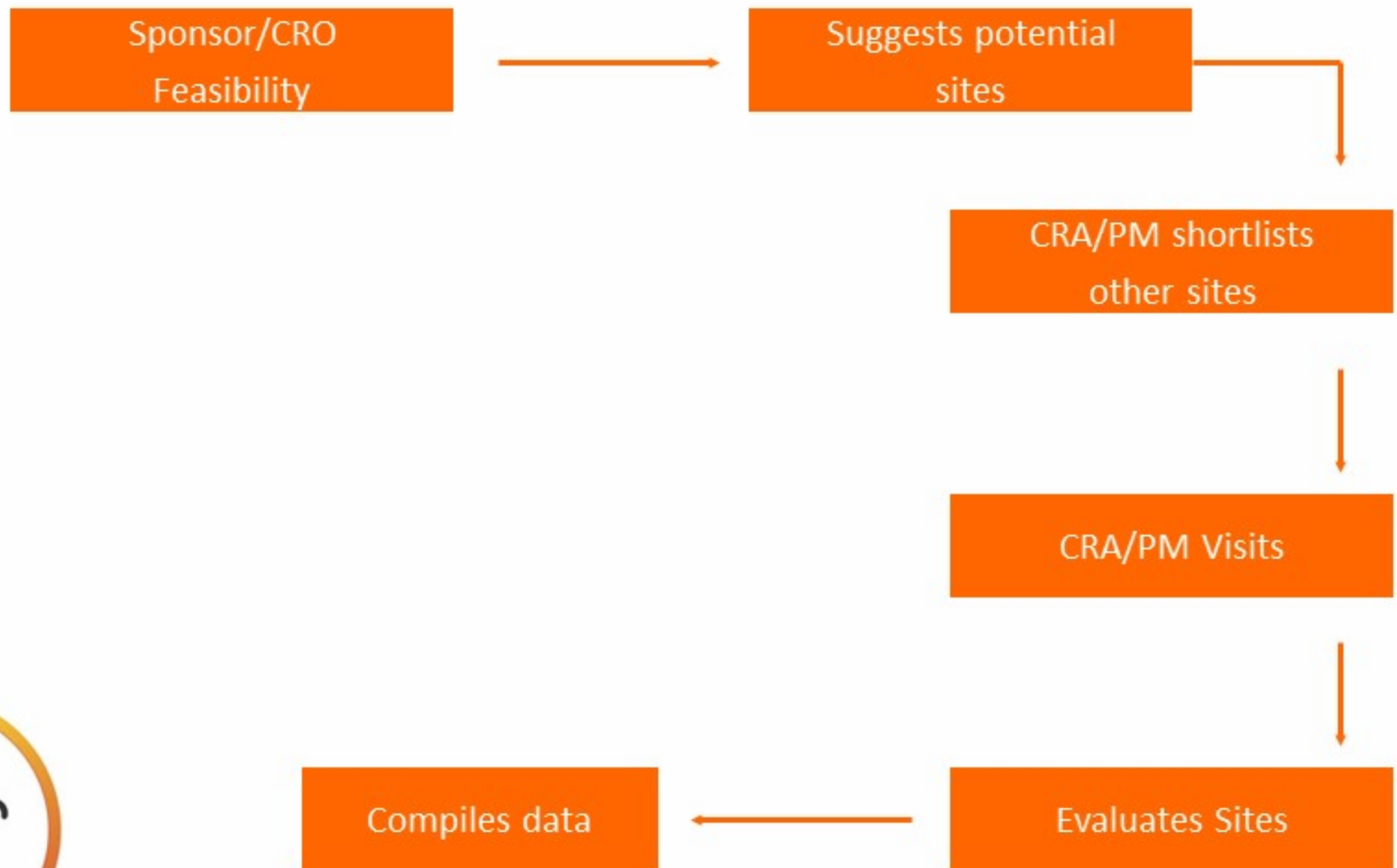
A Typical Selection Process



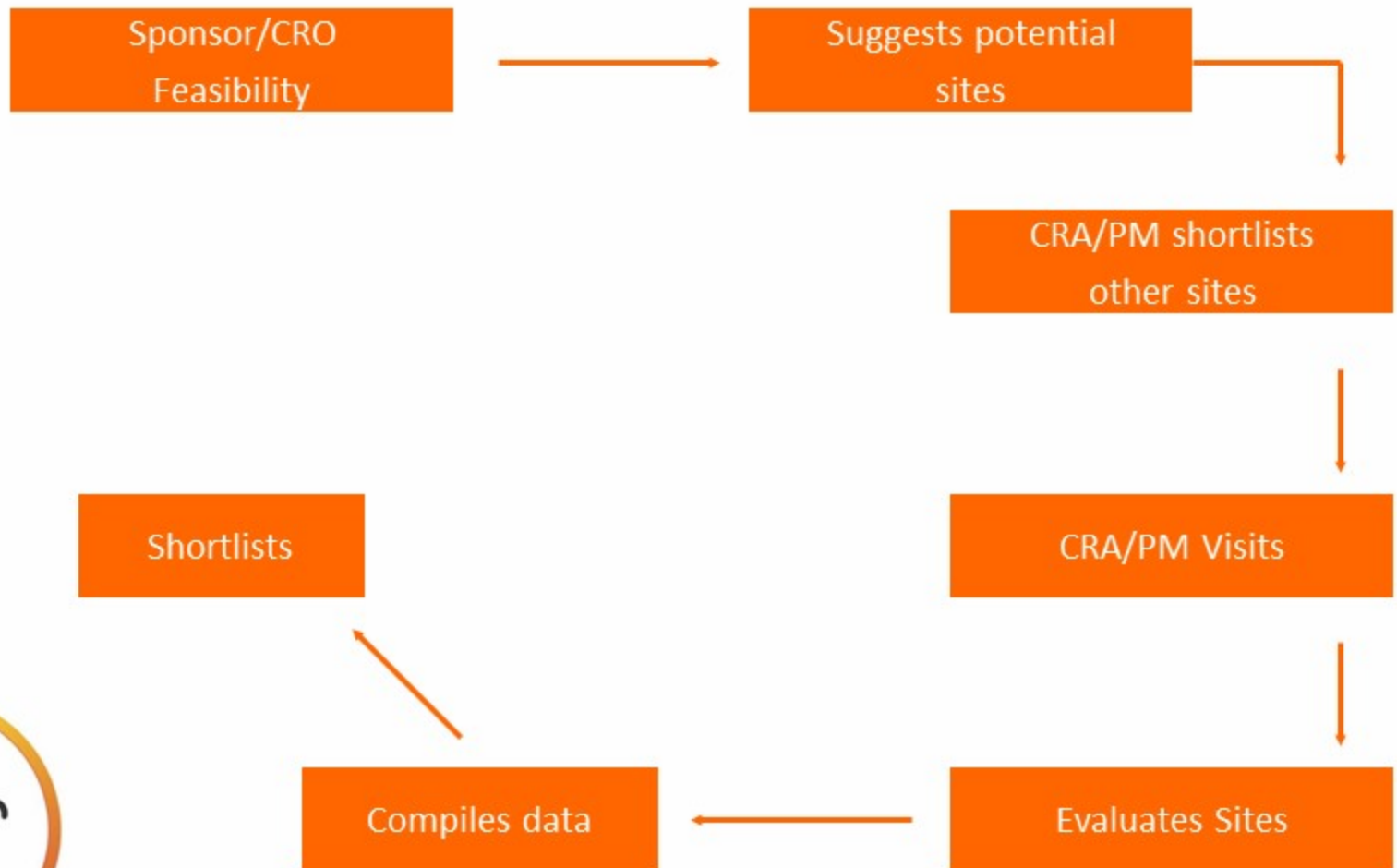
A Typical Selection Process



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A Typical Selection Process



A Typical Selection Process

