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?

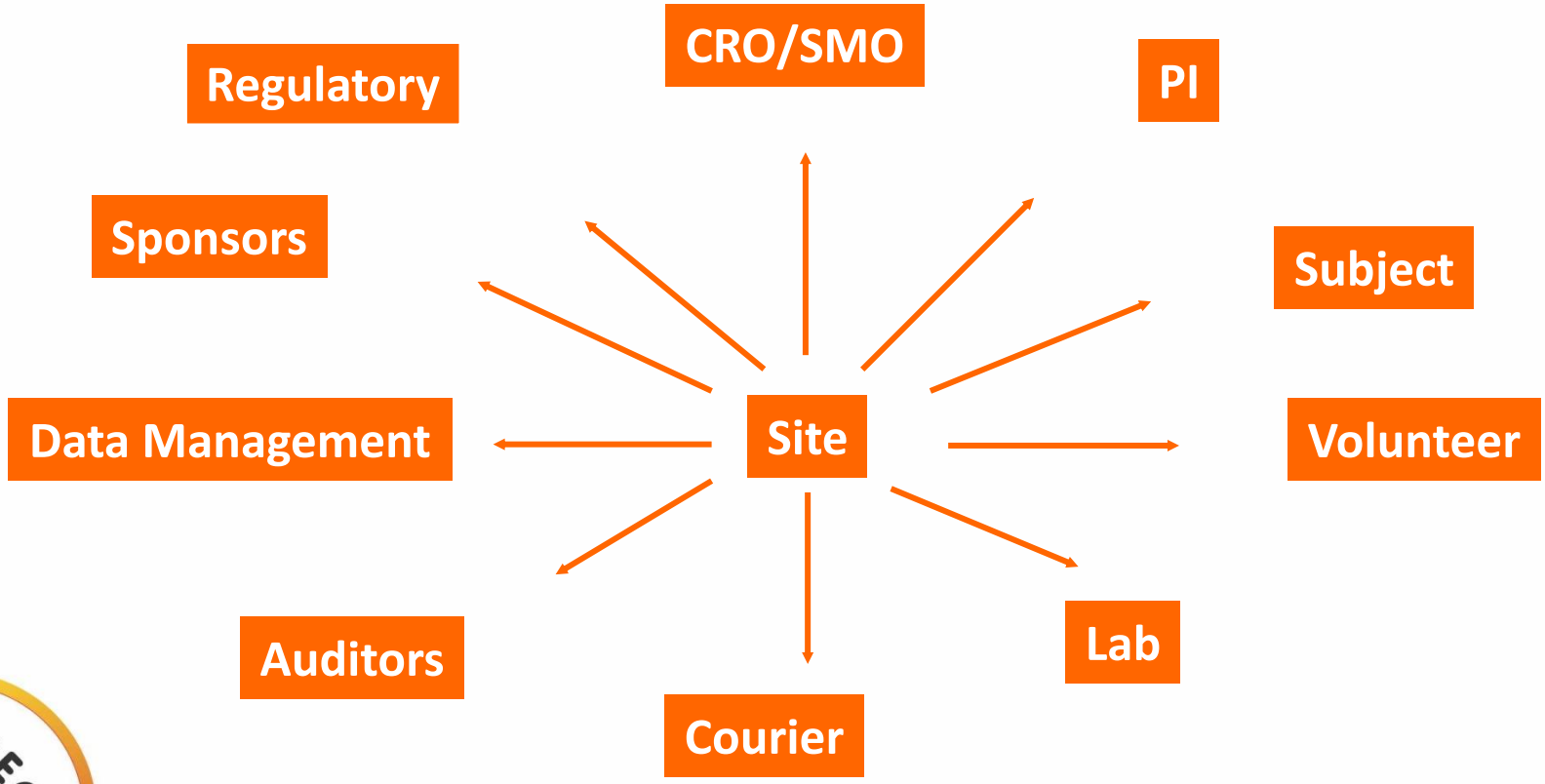
Sites

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

Site - Expectations

- Interesting 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 & Trustworthiness
- Progressive & compatible management
- Organized

Site requirements

- 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

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

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

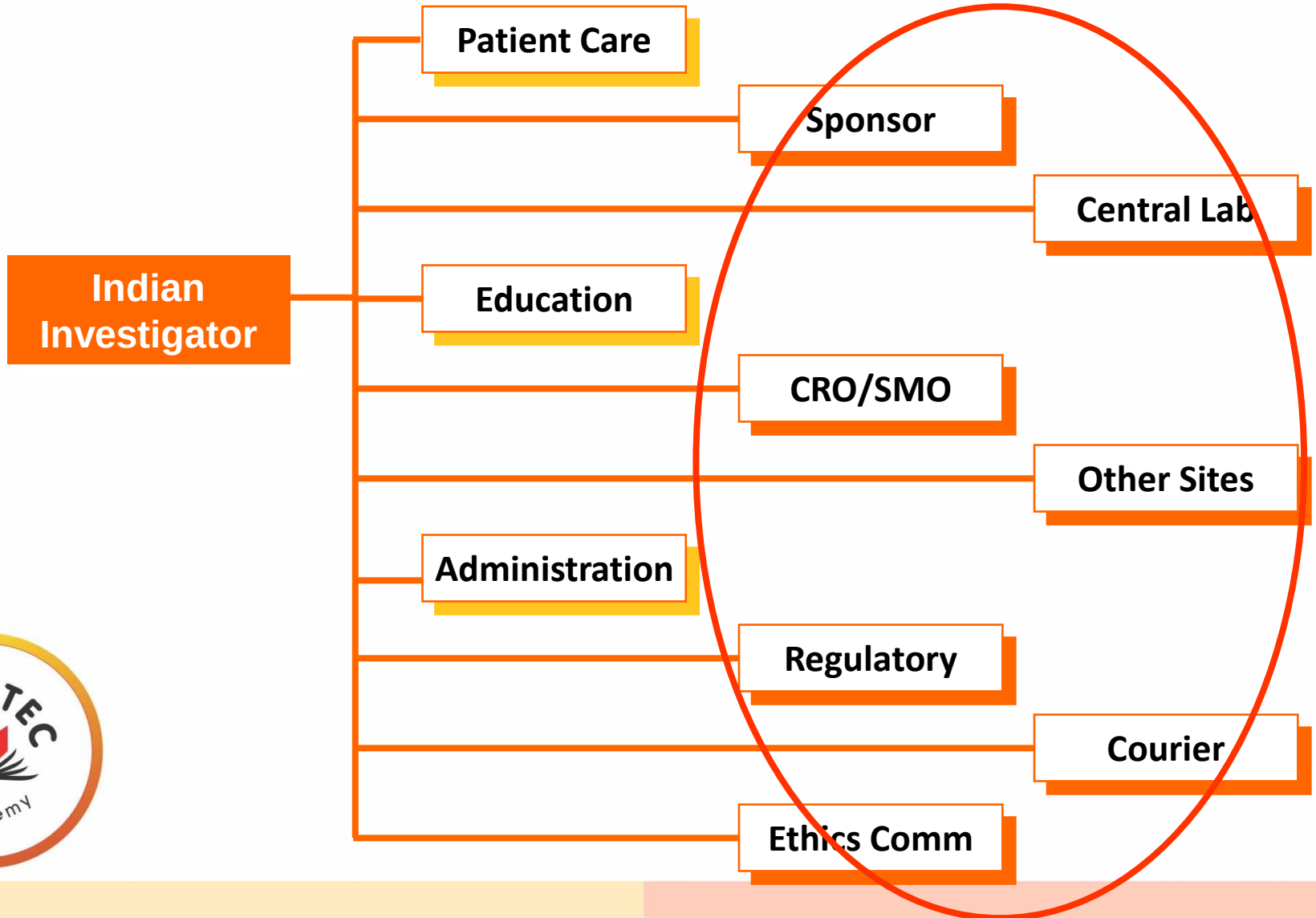
PI Identification

- 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



A Typical Selection Process