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# Agenda



- Theoretical background
- Importance of communication with study site team
- Motivational factors in clinical trials
- Clinical Research drivers
- How to increase site efficiency and productivity
- What task needed supplementary training at the site level
- Preferred Training Methods
- Summary

# Investigator's Motivation



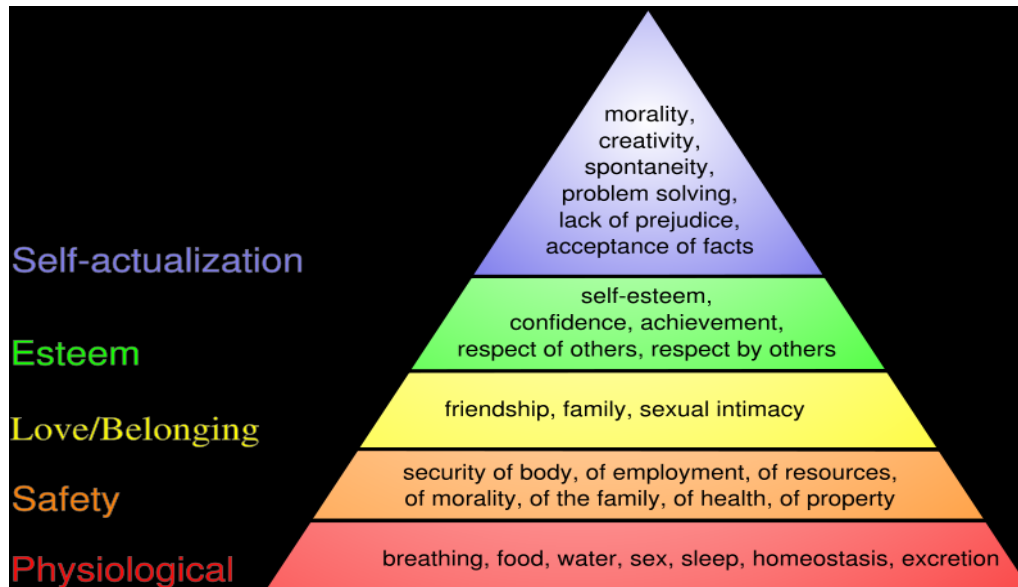
- **Motivation** refers to the initiation, direction, intensity and persistence of human behavior
- **Motivating** people  process of getting people to move in the direction you want them to go



# Motivation



- People are motivated to do something if they think it will be worth their while
- Motivation is initiated by someone recognizing an unsatisfied need



# Motivation-messages



## No simple solution to increase motivation

- Individual need and aspirations
- Intrinsic and extrinsic motivators
- Expectation of reward
- Social context

## Important motivation factors

- Expectation
- Goal-setting
- Feedback
- Reinforcement

# Definitions

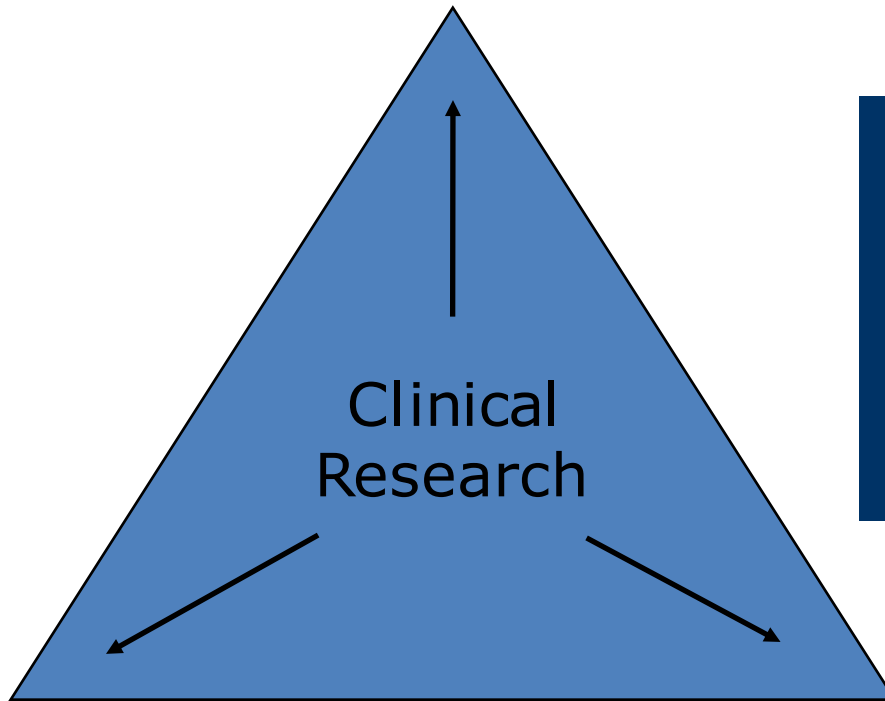


- Intrinsic motivation occurs when people are internally motivated to do something because it either brings them pleasure, they think it is important, or they feel that what they are learning is morally significant
- Extrinsic motivation comes into play when a subject is compelled to do something or act a certain way because of factors external to him or her (like money or good grades).

# Clinical Research Drivers



Inv. Motivation



External support

Site infrastructure

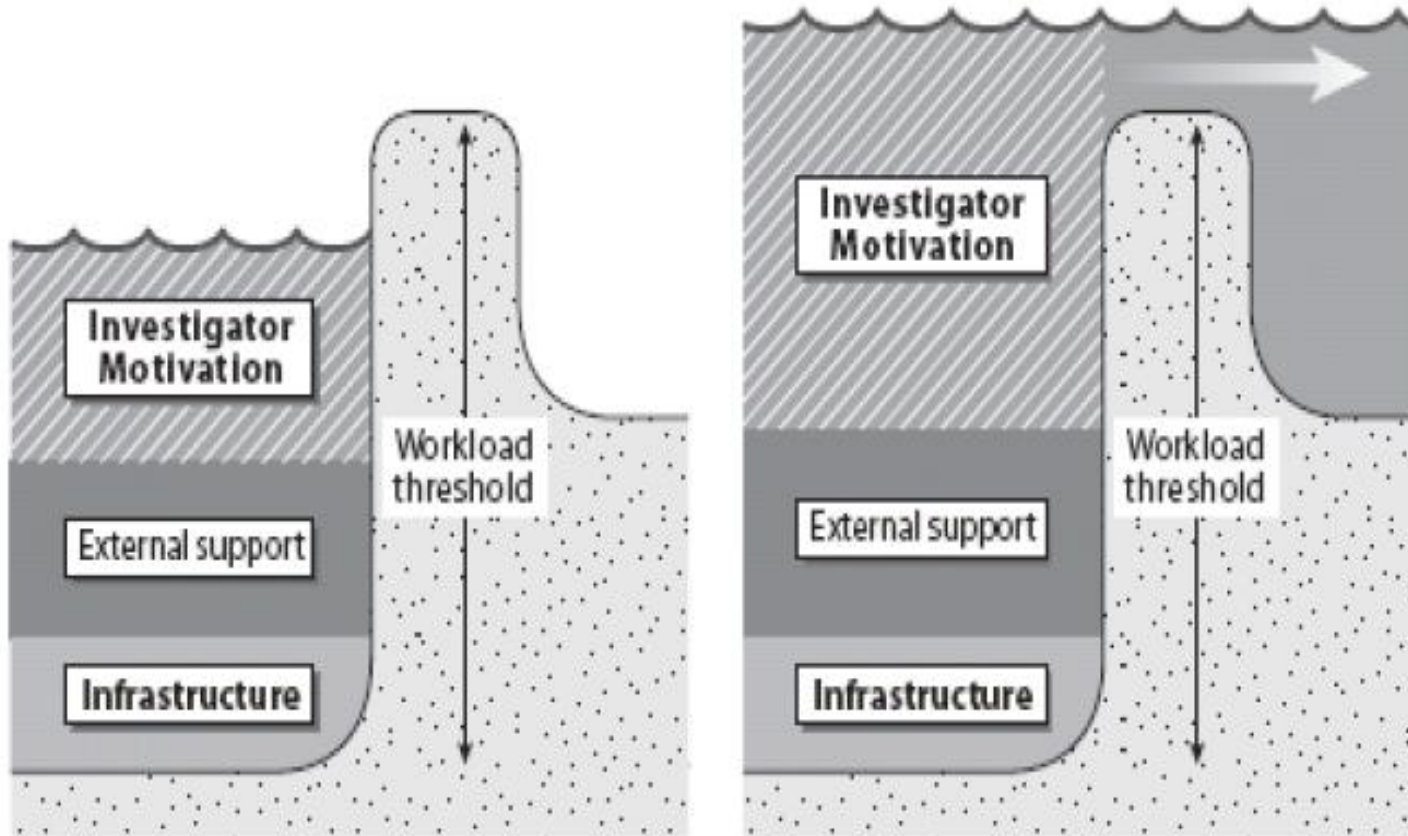
**Changing the parameters of any one of the three constraints will have a direct impact on the remaining two**

# Clinical research Goals



- Maximised efficiency and site productivity
- Minimised the efforts to sustain the clinical research

# Clinical research drivers



\* Journal of Clinical Research Best Practice, 2008

Premier people. Premier process. Premier performance.

# Sites with good infrastructure

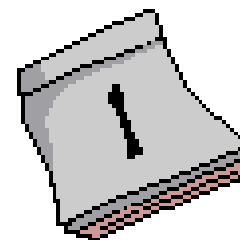


- Good internal organisation of workload distribution
- Internal SOPs
- Employ study coordinators and site staff

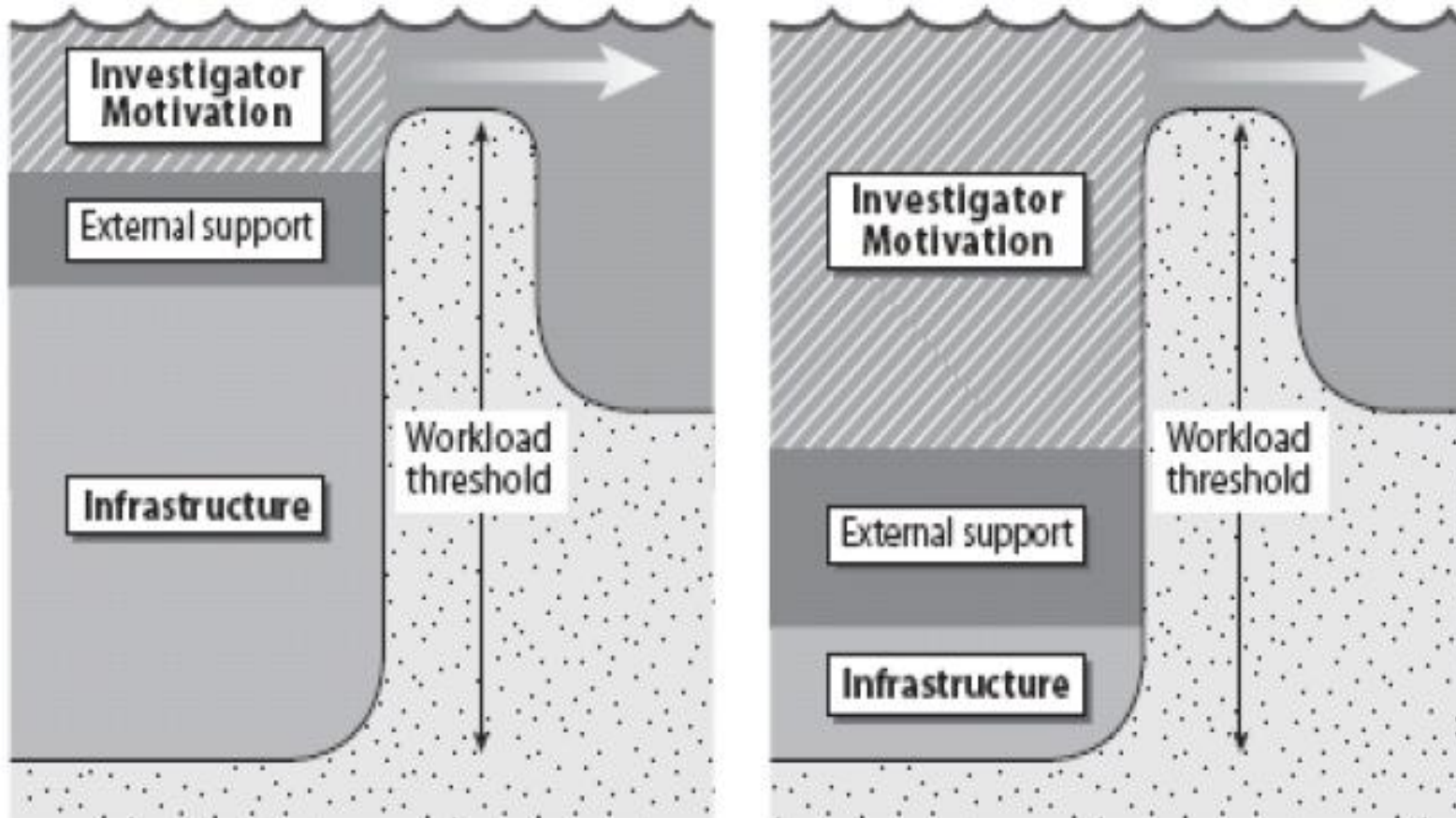
# From first moment have a good communication



- When perform feasibility check :
  - Investigator's present schedule
  - Professional obligation
  - Facilities
  - Staff with the study's requirements training
  - Correct estimation of potential patients (database/2/2PC\*scrfailure)



# Sites with good infrastructure



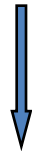
\* Journal of Clinical Research Best Practice, 2008

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# Real-world life in clinical research



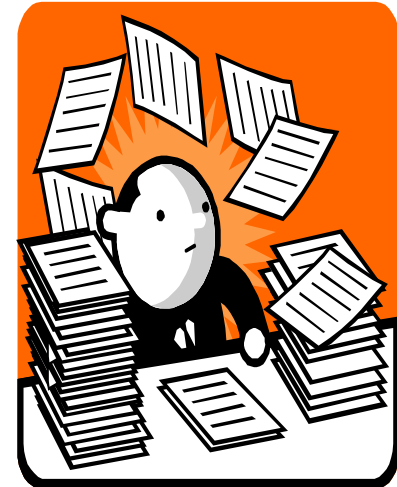
- Criteria of site selection done by Sponsor or CRO:
  - KOL at sites
  - Patient pool
  - Site experience with disease or medication



– Poor research infrastructure!



- If relationship between Investigators and study staff not working, Sponsor/CRO must increase efforts:
  - Site calls
  - More Newsletters
  - Graph with recruitments targets
  - More MV
  - Increase contacts to resolve queries



# Minimizing Investigators' workload



- Simplify Registration Documents
- Simplify the Ethics Review/IRB process
- Provide Patient Support Materials
- Provide Effective Training
- Provide Intuitive Study Materials

# Planning for success not rescue



- **What motivates Investigators to join the study?**

- Scientific interest/recognition/publication etc.
- Benefit of better treatment options for patients
- Lower costs of treatment for site and/or patients
- Appropriate fee
- Funds for improved equipment/facilities

- **What motivates patients to join the study?**

- Access to relief of symptoms
- Long term treatment of illness
- Regular check ups and contact with medical staff (TLC)
- Reduced treatment or clinic attendance costs
- Education and information about their condition/study/treatment options
- Meeting others with same illness

- **What works best per indication and per country?**

- **What really make the difference?**



# Motivated investigators



- Have the “energy” to meet the study workload
- Complete the Forms
- Submit data on time
- Remained positive thought the study



# Investigator's training



# Investigators Training



- How to ensure site staff training?
  - Investigator's Meeting ( preferably face to face)
  - PSV/SIV ( not preferred WebEx)
  - WebEx Interactive Training
  - CD-ROM
  - Help line for Investigators

# Investigators Training



- All Individual task at the trial site needs training
  - Randomization
  - Physical examination
  - Medication dispensing
  - Ordering additional supply
  - Farmacovigilance reporting
  - Study workflow

# Site Training



- Having a study coordinator trained and being familiar with the study increase the site value
- Clinical research success is assured by a better training of site coordinator
- New training trends are the key to ensure the both theoretically and practically training of study coordinators

# Site Training



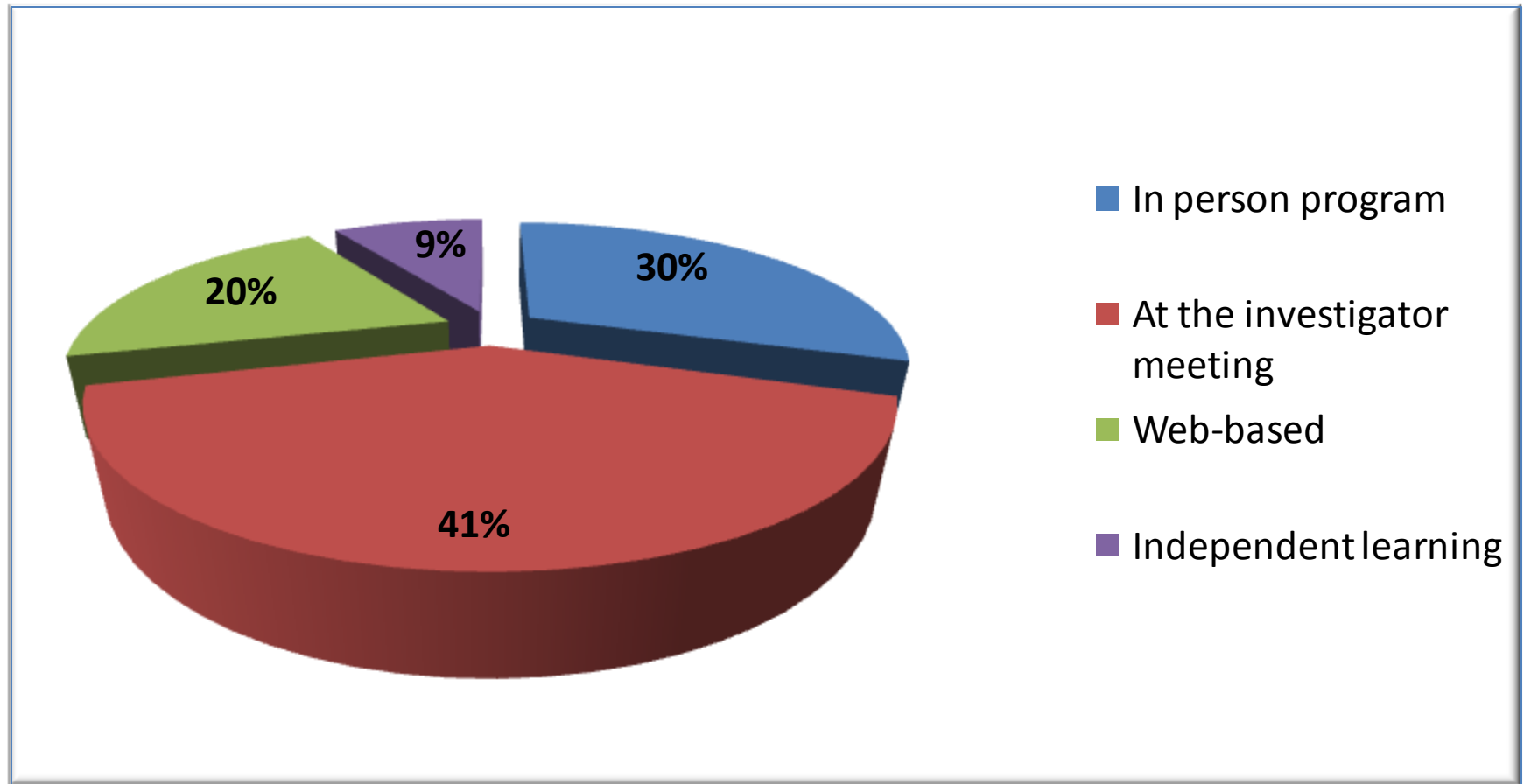
- Trained site staff is a key success factor for pharmaceutical and biotechnology companies
- How to administer Inform Consent
- Have to anticipate slow recruitment
- Recruitment strategies
- Tools of success for clinical trials
- Audit preparation
- Advantages and disadvantages of different study design

# What others trainings needs the site



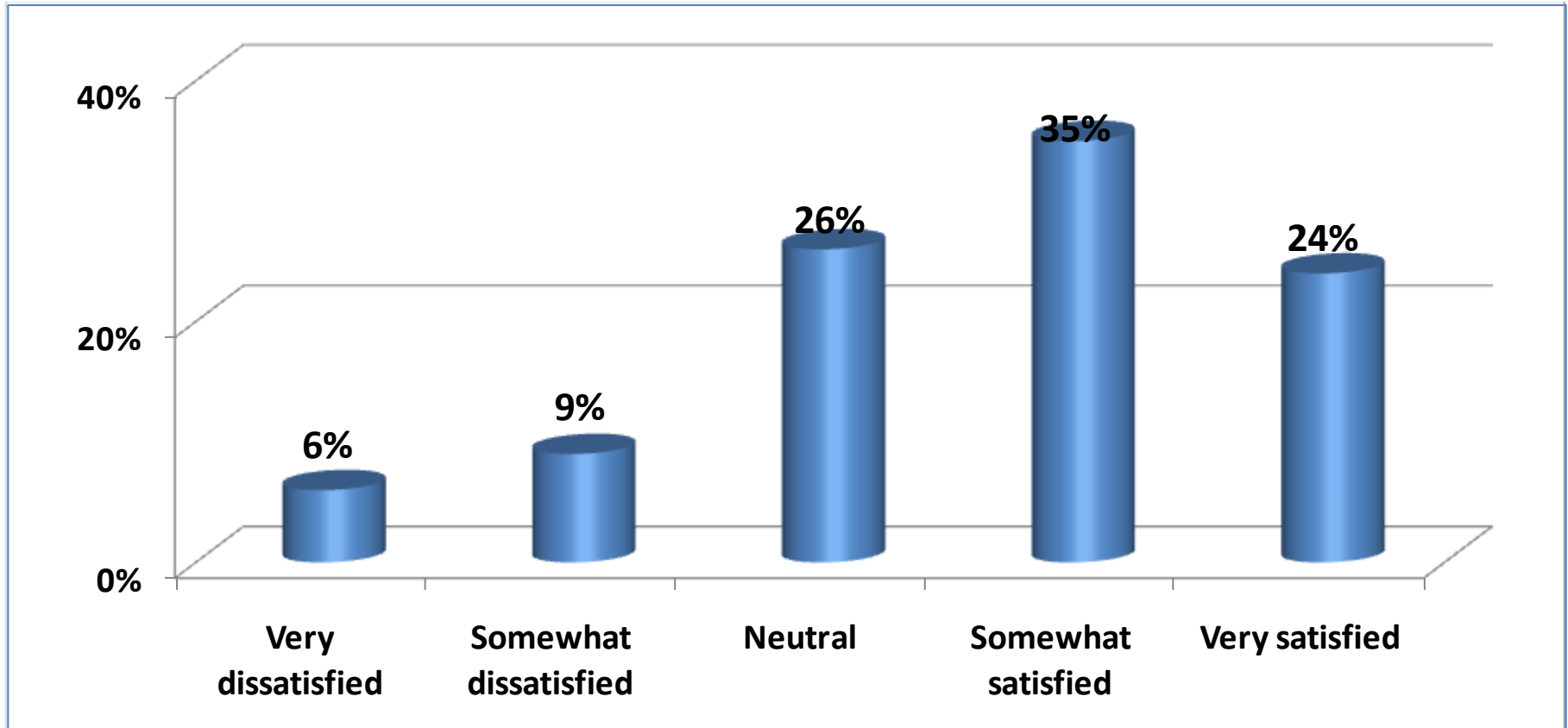
- How to conduct clinical research
- What site infrastructure is required
- What is the proper workflow in research
- Business process improvement at site level
- Budgeting
- Marketing
- Data capture

# Preferred Training Method



Source: Tufts CSDD Survey of 3,516 Investigative Sites, 2010

# Overall Site Satisfaction with Sponsor Training Initiatives



Source: Tufts CSDD Survey of 3,516 Investigative Sites, 2010

# Monitor and site staff = SPORTS TEAMS



- **S**pace/facilities
- **Pi** (qualified and committed)
- **O**rganizational support
- **R**esearch Interest ( clinically and financially feasible)
- **T**ime
- **S**taff
  
- **T**raining in specific areas
- **E**fforts
- **A**vailable subjects
- **M**entor
- **S**ponsor



# Summary

- Invest time for a good site selection
- Understand the site needs and support them
- Have a good communication with Investigators teams
- Be accessible
- Discuss projects internally in the site team
- Try to diminish site workload
- Share the successes with PI/ sub investigators

# Summary

- Give investigators training and guidance
- Used planning tools and create achievable goals
- Be prepared for every single meeting or telephone call, by having clear goals
- Divide responsibilities – offer help and assistance, but don't do their work
- Be prepared for difficulties and do not take them personally





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**Thank you!**