Conducting International Clinical Research: What Resources are Necessary?

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Study participants need to answer 3 questions:

- **Is the research question important?**
- **Is the study design appropriate and feasible?**
- **What will be my role?**

Need a collaborative group (James D. Campbell)

- **Competent & knowledgeable**
- **Cooperative & motivated**
- **Flexible**

Need appropriate resources

- **Must have on-site human resource support**
  - **Lead site investigators**
  - **Research co-ordinators**
- **Must have a well-structured protocol**
- **Must have a well-structured manual(s) of operations**
- **Investigator training**
- **Provision of support staff at a methods or coordinating centre**
- **Web-based Randomization**
- **Electronic Datafax collection system**
- **Funding**

Site investigators must be able to support the following:

- **Responsible for the overall running of the trial at the clinical centre**
  - **Local Ethics Approval**
  - **Patient safety**
  - **Informed consent**
  - **Trial protocol adherence**
  - **The quality and integrity of the resulting data**
  - **Staff training**
  - **Attend investigator meetings**
  - **Regular communication with coordinating centre**