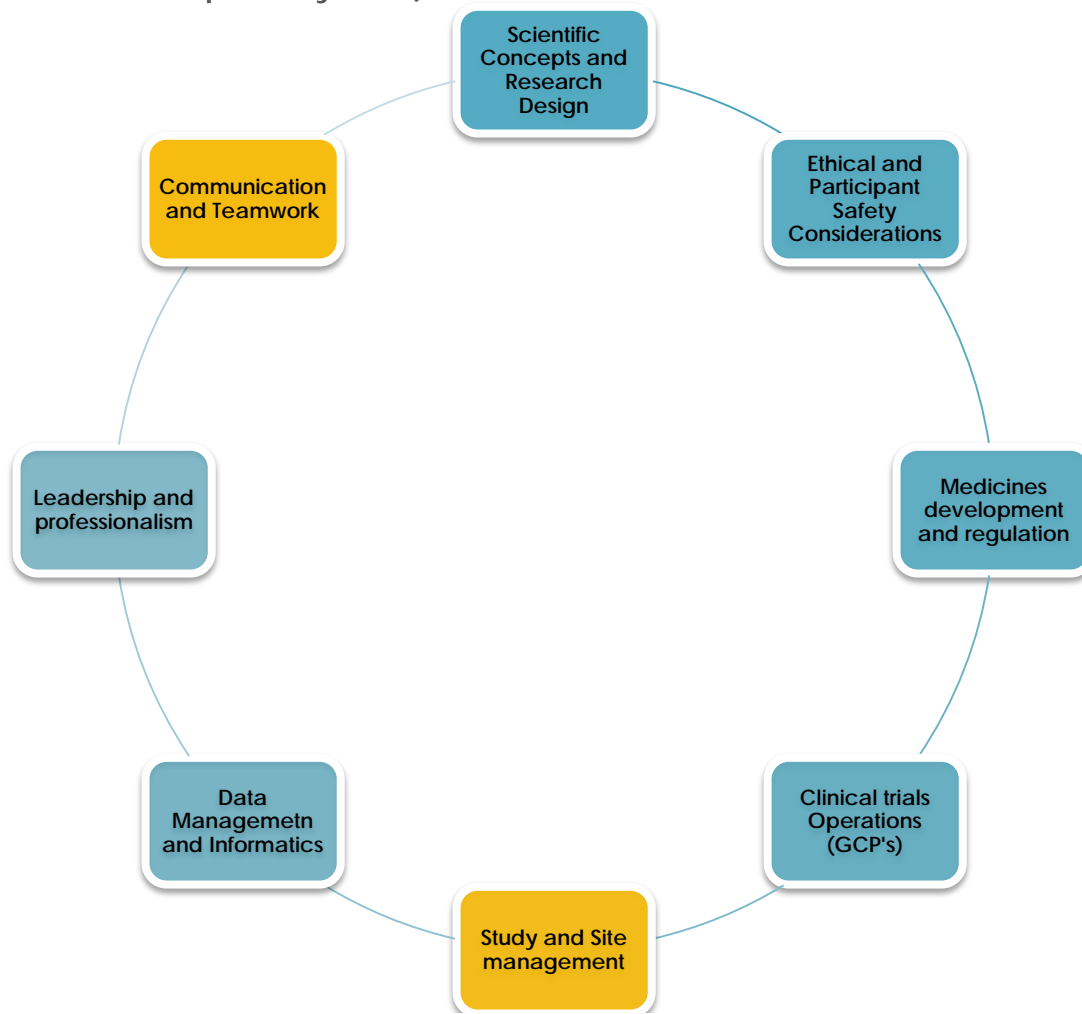# What will be discussed ….

- Clinical trial management – a core competency

- Clinical trial Tasks – knowing is not enough

- Project Management – Strategy for control

Clinical trial management – a core competency
(Joint Task Force for Clinical Trial Competency 2014)

Journal of Clinical Research Best Practices Vol. 10, No. 6, June 2014

Clinical trial Tasks – knowing is not enough

- Initiation
- Project set up
- Centre set up
- Recruitment
- Follow-up and analysis
- Trial close

- **Crisis Management?**

What's is Project Management

- **A Project is:**
  - An undertaking with a definitive beginning and end

- **Management is:**
  - Getting things done effectively through people

- **Project Management is:**
  - The EFFECTIVE use of people and resources to COMPLETE a set of specific tasks in a given time
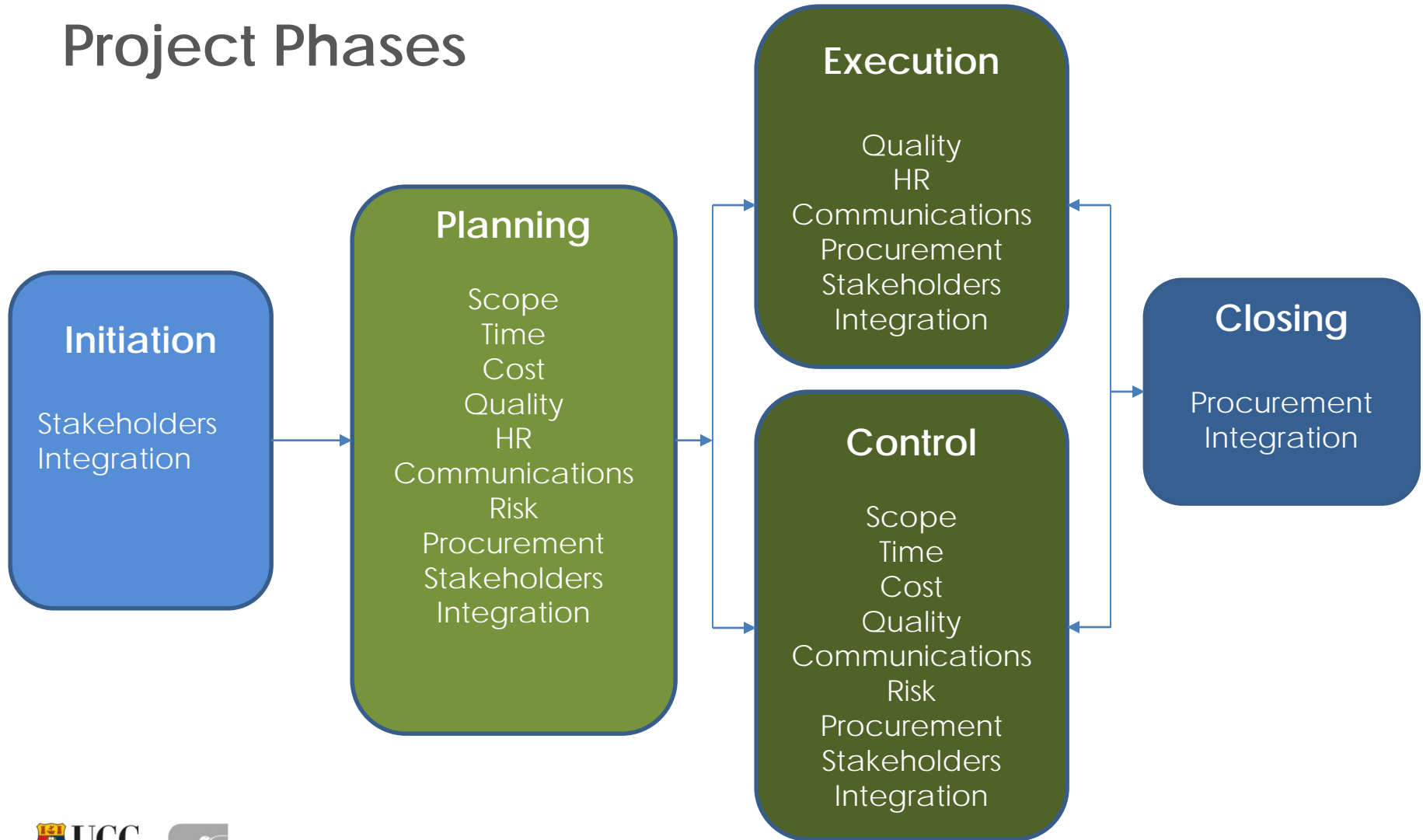

I think we need a good Project Manager to coordinate our efforts...

Project Management knowledge areas

Figure 1 – Knowledge Areas

Project Phases

Initiation

Stakeholders
Integration

Planning

Scope
Time
Cost
Quality
HR
Communications
Risk
Procurement
Stakeholders
Integration

Execution

Quality
HR
Communications
Procurement
Stakeholders
Integration

Control

Scope
Time
Cost
Quality
Communications
Risk
Procurement
Stakeholders
Integration

Closing

Procurement
Integration

Resources

- CRF-C
- Project Management Institute (PMI)
- International Project Management Association (IPMA)
- Core Competencies
  - **Sonstein, et. Al. (**2014)Moving From Compliance to Competency: A Harmonized Core Competency Framework for the Clinical Research Professional. Journal of Clinical Research Best Practices Vol. 10, No. 6, June 2014
  - NHS National Institute for Health Research - Trail Mangers Network. Task, Knowledge and Competency Framework for Trial Managers 2012