

INTERNATIONAL PERCEPTION OF COMPETENCE

Needs For Clinical Research Education

Stephen Sonstein, PhD

Honorio Silva, MD

Survey Objectives

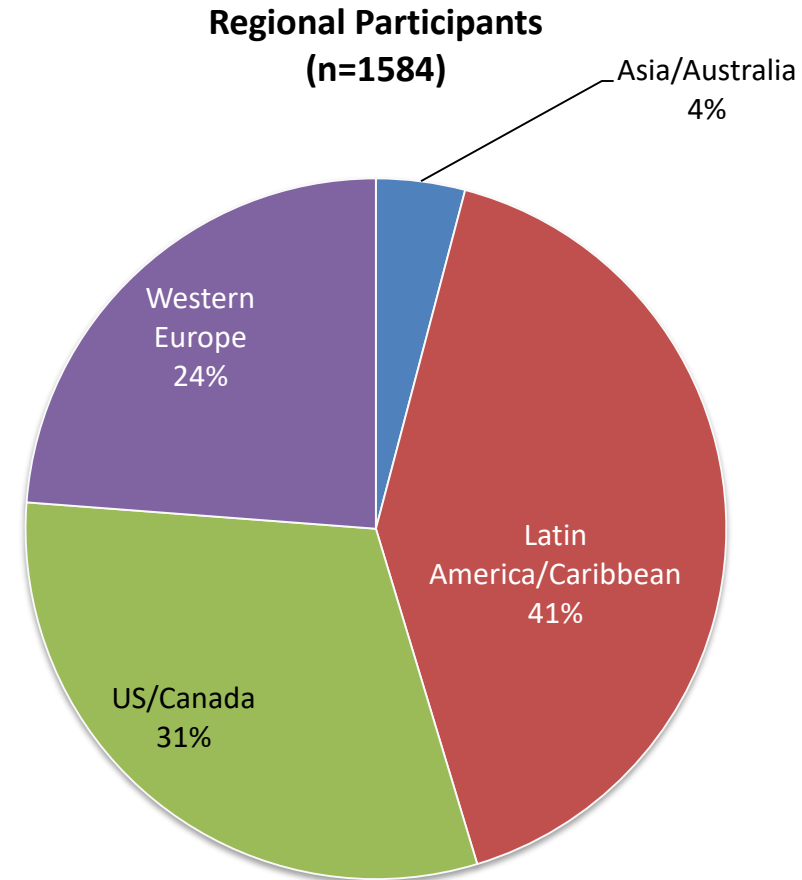
To validate JTF domains/competencies through perceptions of clinical research professionals.

How do the competencies relate to:

- Roles, Job Titles
- Perceptions of competence and relevance
- Educational Levels
- Educational Needs
- Identify gaps for future study and workforce development

Demographics by region and function

Role	#
Clinical Research Coordinator/Research Nurse	559
Research Administrator/Project Manager	357
Principal Investigator/Co-investigator	354
Clinical Research Associate/Monitor	177
Regulatory Affairs Professional	90
Data Management Professional	47
Others	154
Total	1738



Scale of Self-Assessed Responses

Competence:

0 Never been exposed to this content

1= Aware of the content, but never needed to become further informed;

2= Exposed and sufficiently aware of content that I can look up what might be necessary for my job;

3= Competent–Able to interpret or discuss concepts and use knowledge to solve simple problems based on application concepts;

4 = Mastery–able to apply knowledge to complex problems, integrate information and create solutions

Relevance:

0 = unnecessary, no relevance to my role;

1 = has some relevance to my role, but not my responsibility;

2 = relevant to my role, but not a major component;

3 = significant to my role and part of my job responsibilities;

4 = major part of my responsibility or supervisory expectations

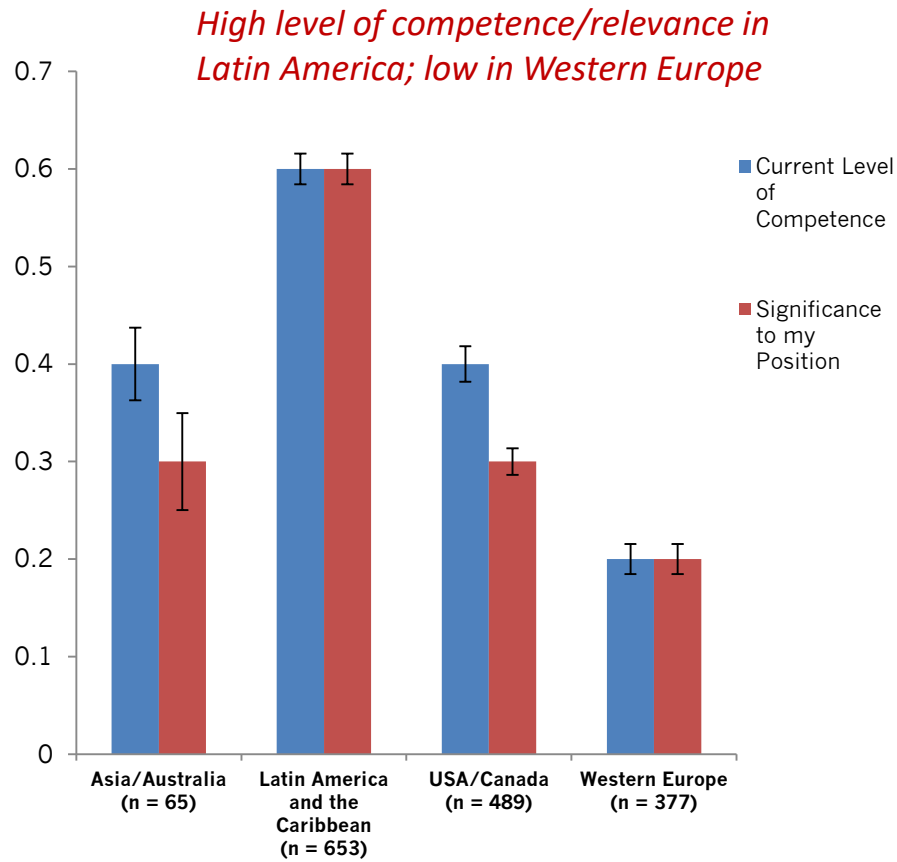


Scale Rearrangements for Statistical Analysis

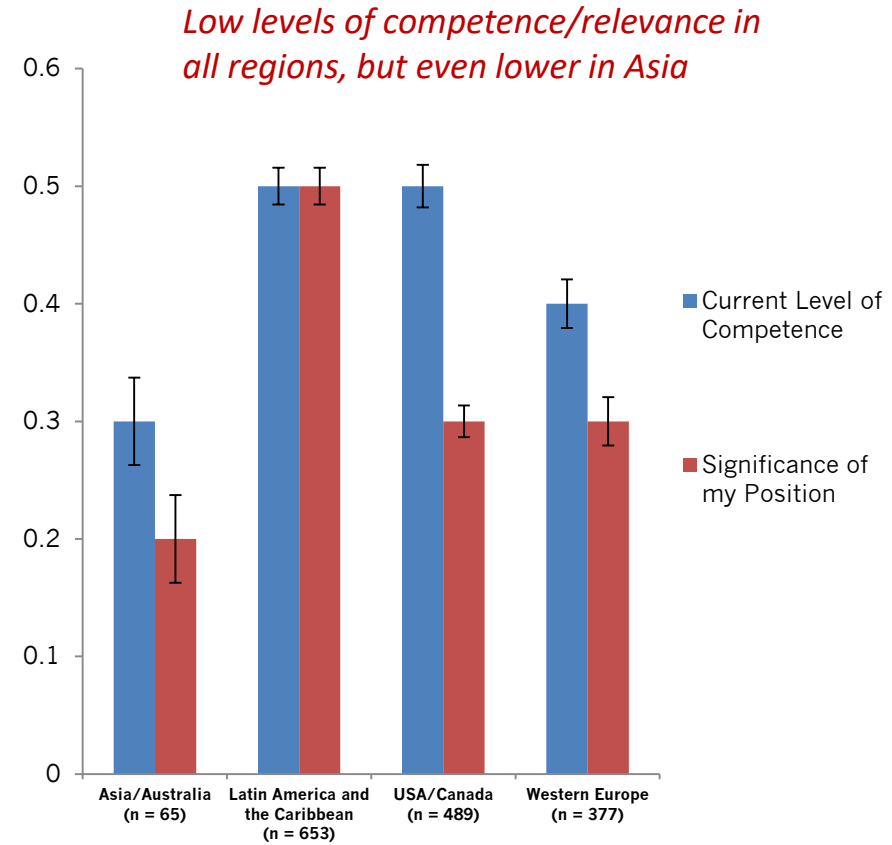
Perceived need for training

Domain	Need for Training (% yes)			
	PI	CRA	CRC	RM
Scientific Concepts and Research Design	61	57	48	44
Ethical and Participant Safety Considerations	51	52	48	44
Medicines Development and Regulation	58	58	50	38
Clinical Trial Operations	53	52	45	36
Study and Site Management	62	57	56	48
Data Management and Informatics	60	53	45	36
Leadership and Professionalism	62	62	55	52
Communication and Teamwork	57	57	48	45

Scientific Concepts and Research Design

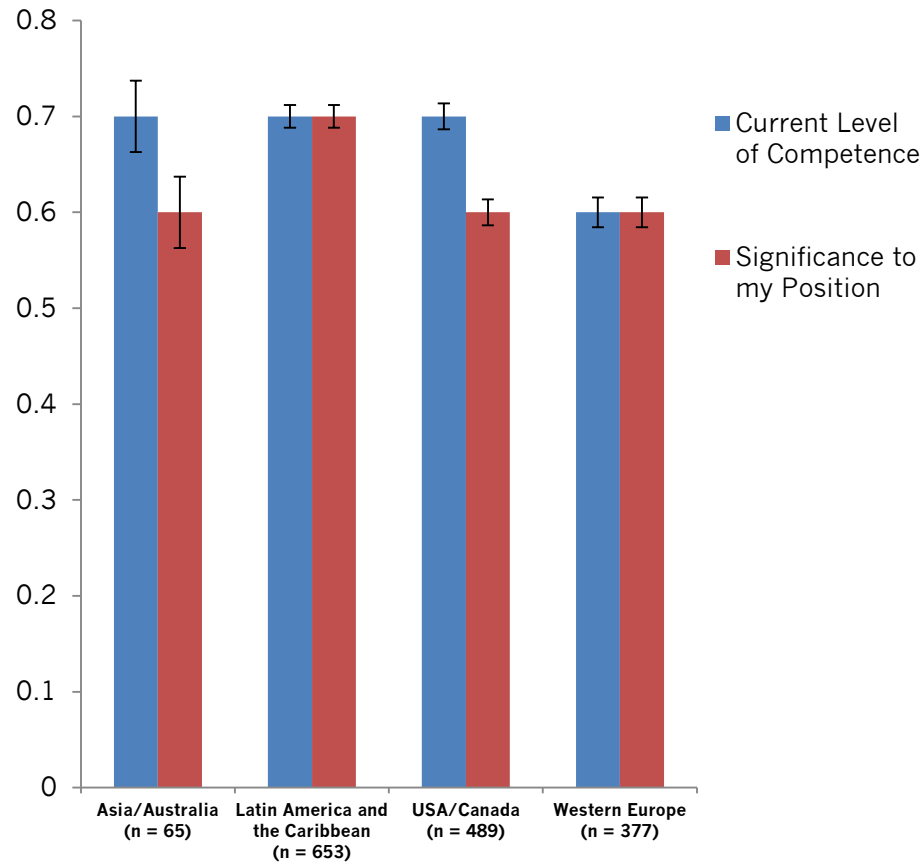


Medicines Development and Regulation

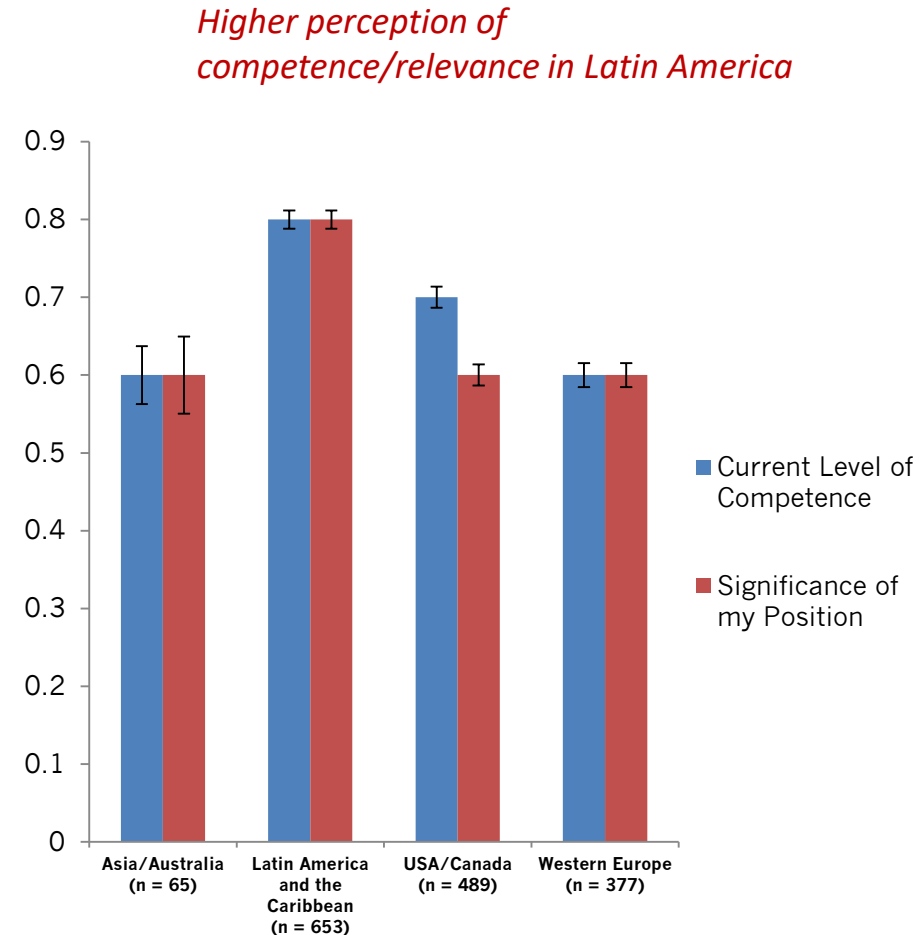


ANOVA: Comparison between regions, *p<0.05, **p<0.01, *** p< 0.001

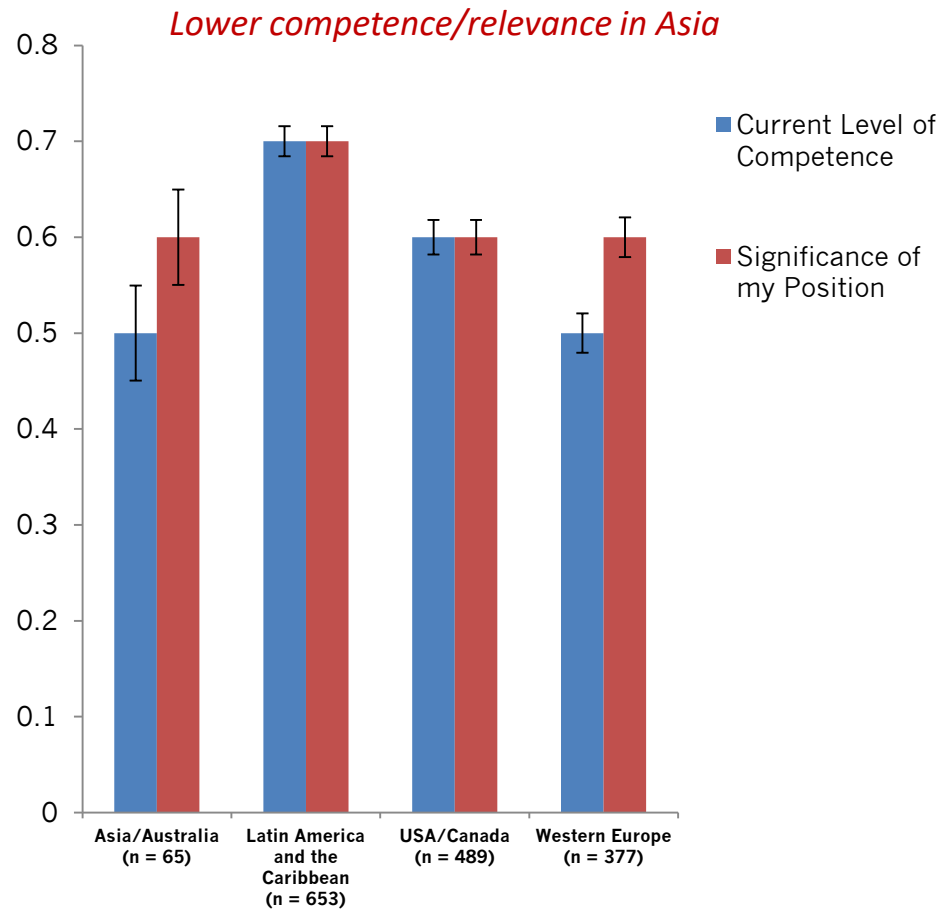
Ethical and Participant Safety Considerations



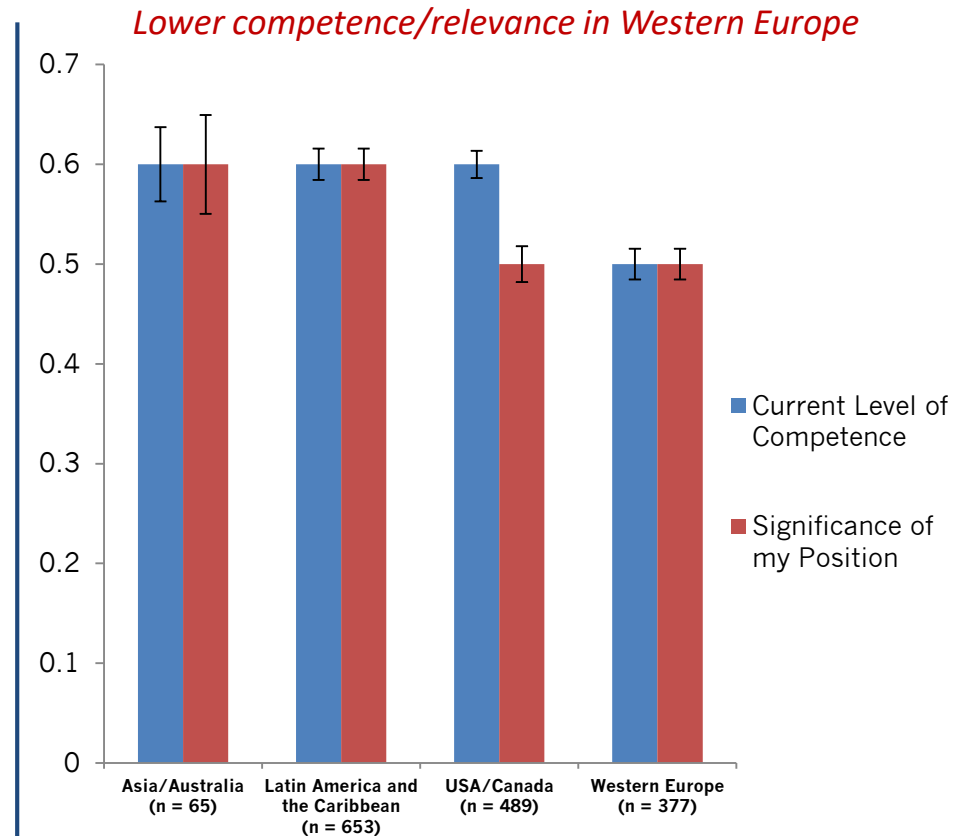
Clinical Operations Domain



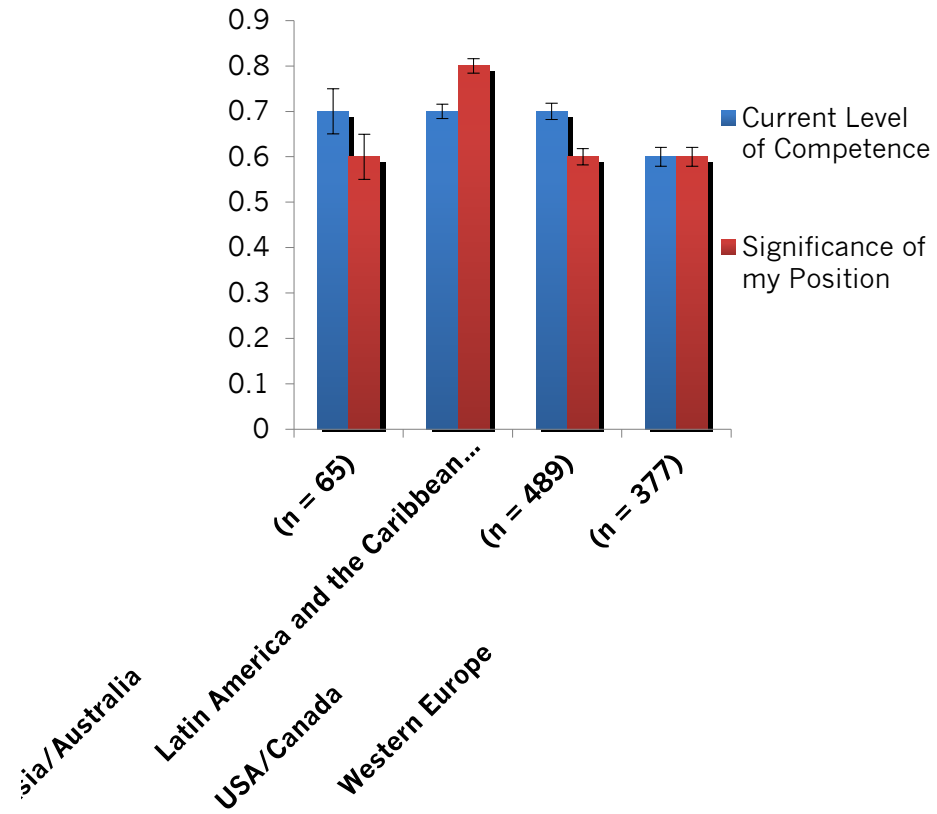
Study and Site Management



Data Management and Informatics

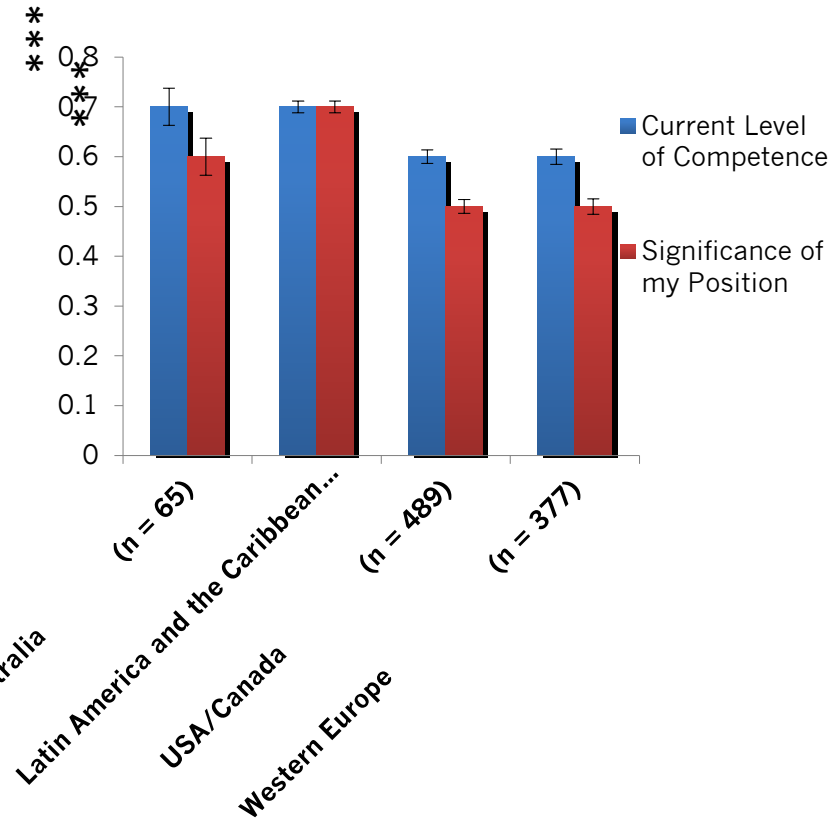


Leadership and Professionalism



Communication and Teamwork

Lower relevance in the USA and Europe



Comments to regional differences

- Need to confirm regional findings (focus groups) or surveys among representative samples from participating countries
- Need to explore further according to source of employment (academic, industry, CROs)
- Questionnaire was conducted in English. Need for language validation to confirm full understanding of the individual competency
- In spite the large sample size, internal regional demographics could skew the interpretation of results
- Several hypothesis can be formulated