The JACIE Accreditation Process

JACIE Office,

Barcelona, Spain

Contents

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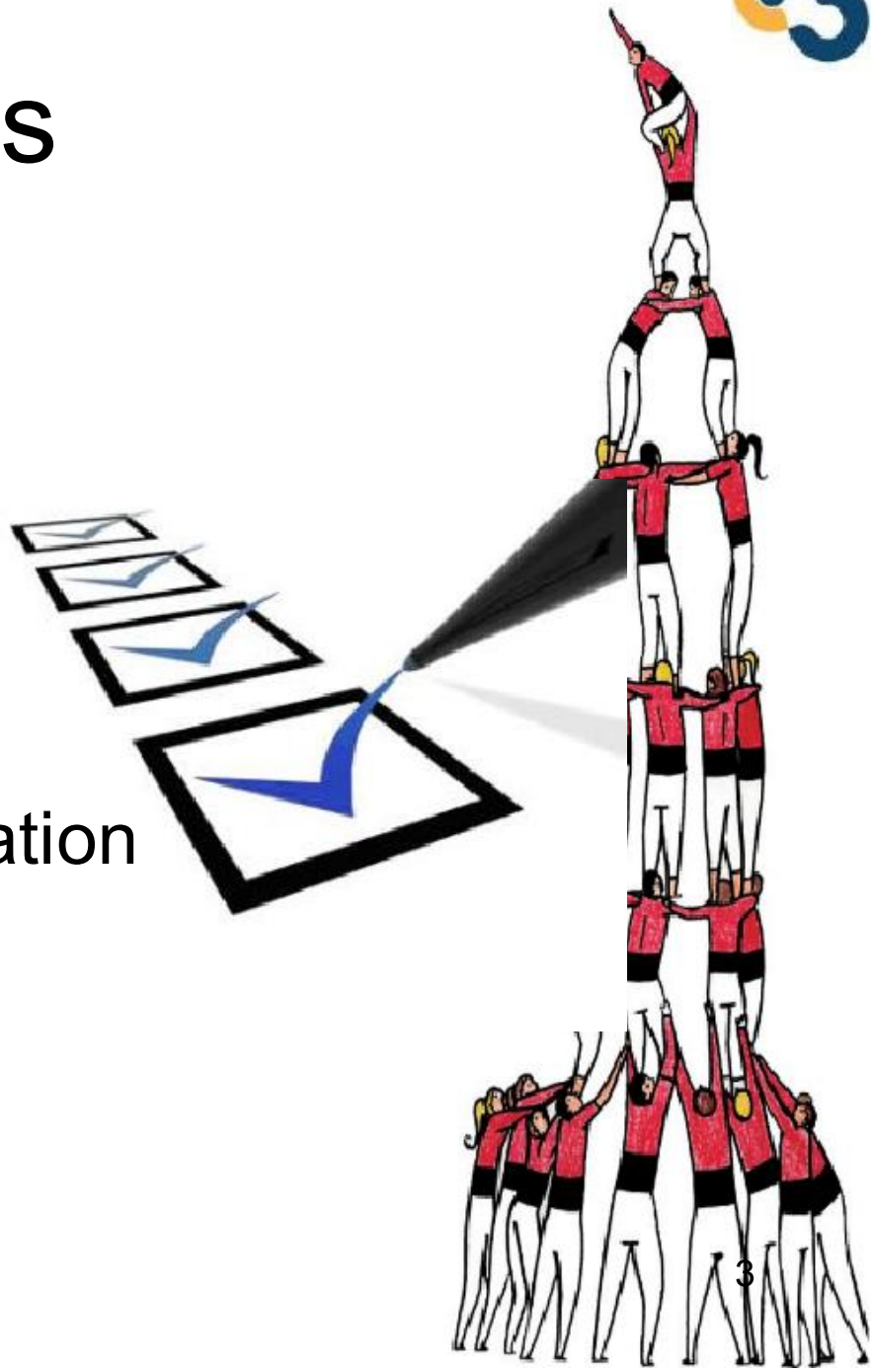
- Preparation by the centre
- Application
- Inspection Checklist
- Pre-inspection documentation
- Inspection



Phases

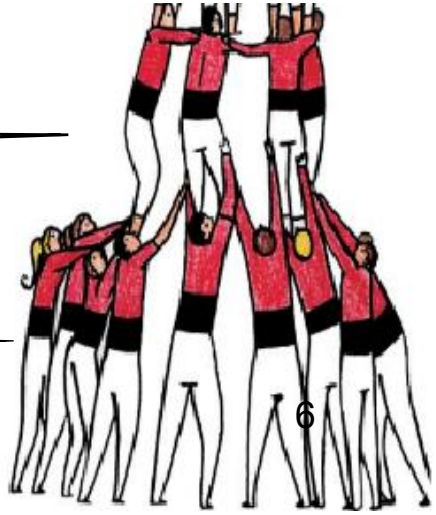
Process

Decision to work according to the Standards

Process

Preparations, working with quality

Decision to work according to the Standards

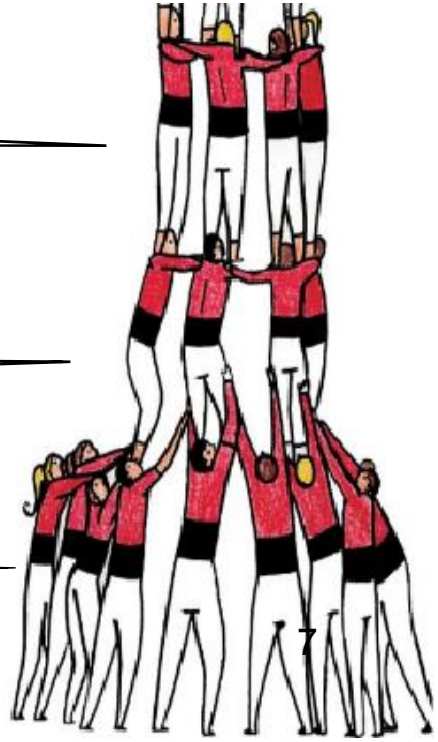


Process

Request inspection

Preparations, working with quality

Decision to work according to the Standards



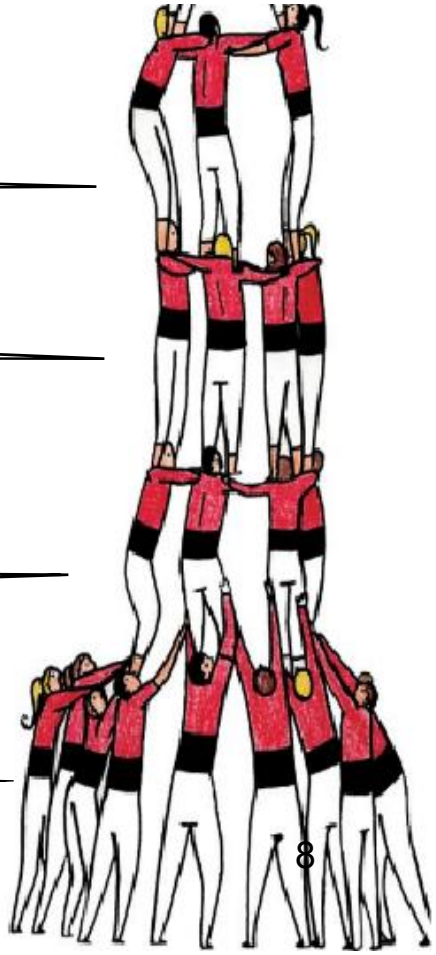
Process

Inspection

Request inspection

Preparations, working with quality

Decision to work according to the Standards



Process

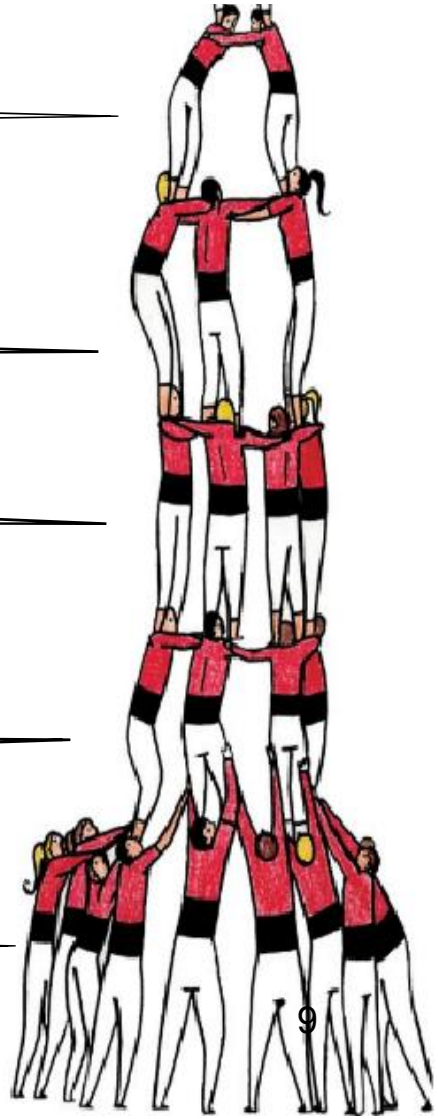
Corrections

Inspection

Request inspection

Preparations, working with quality

Decision to work according to the Standards



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Accreditation

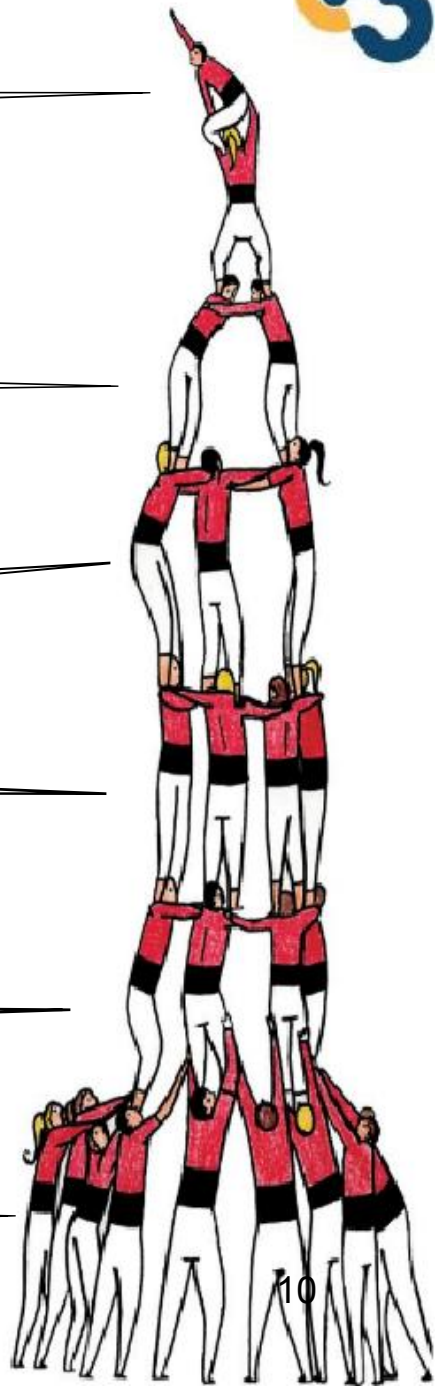
Corrections

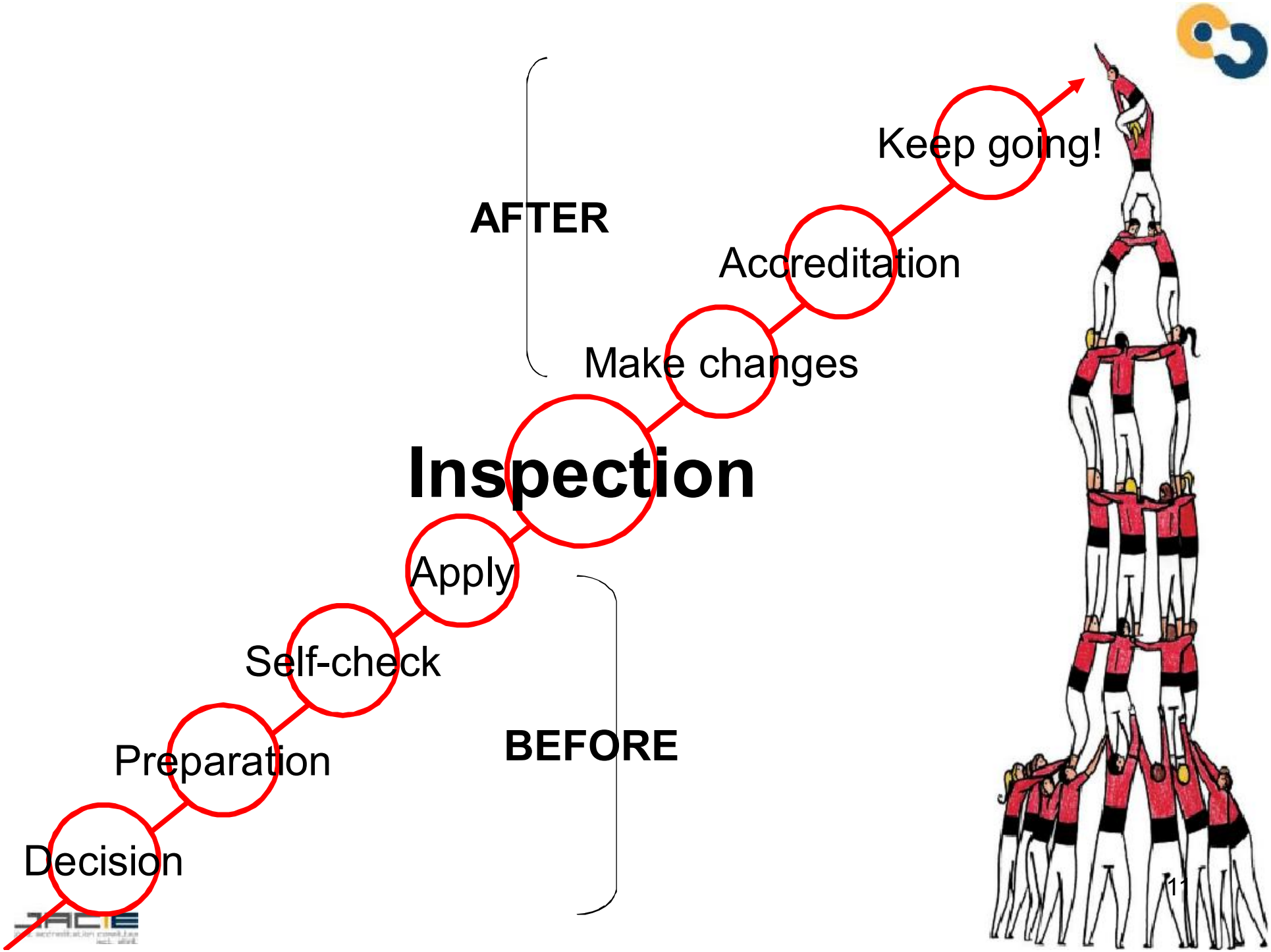
Inspection

Request inspection

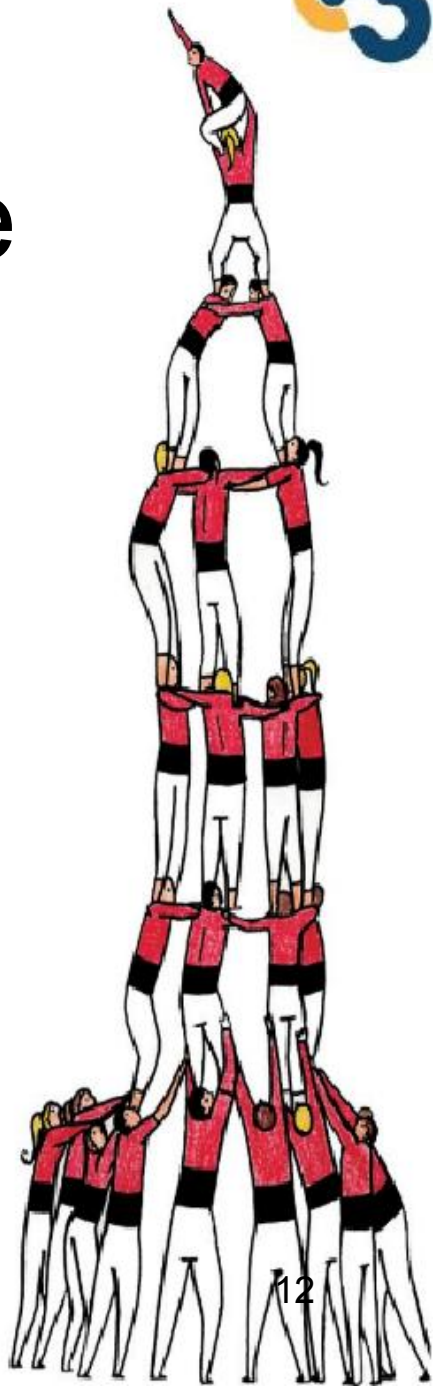
Preparations, working with quality

Decision to work according to the Standards

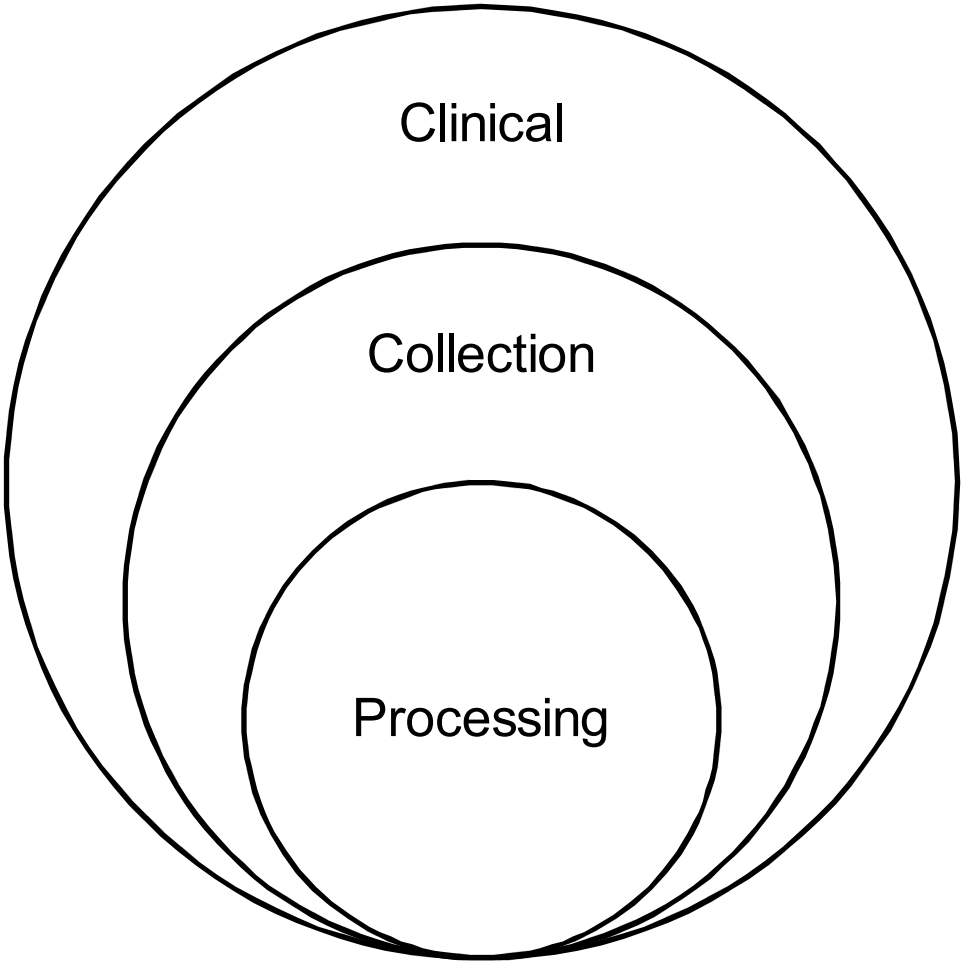



Keep going!
AFTER
Accreditation
Make changes
Inspection
Apply
Self-check
BEFORE
Preparation
Decision

Preparation by the centre



Accreditation

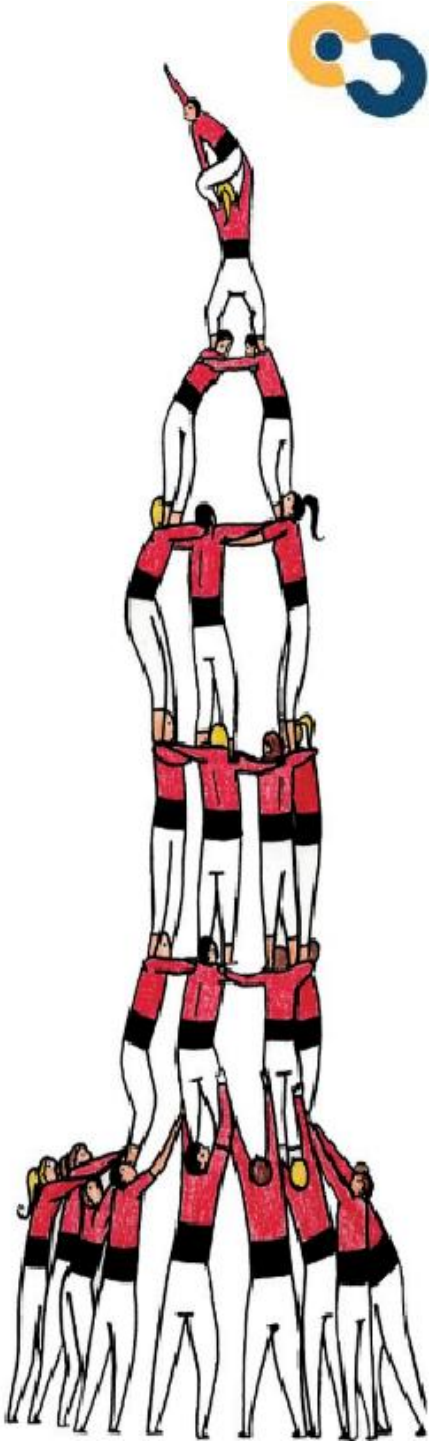


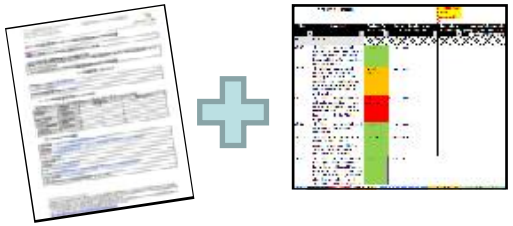
Application

APPLICATION FOR FIRST-TIME ACCREDITATION & RE-ACCREDITATION

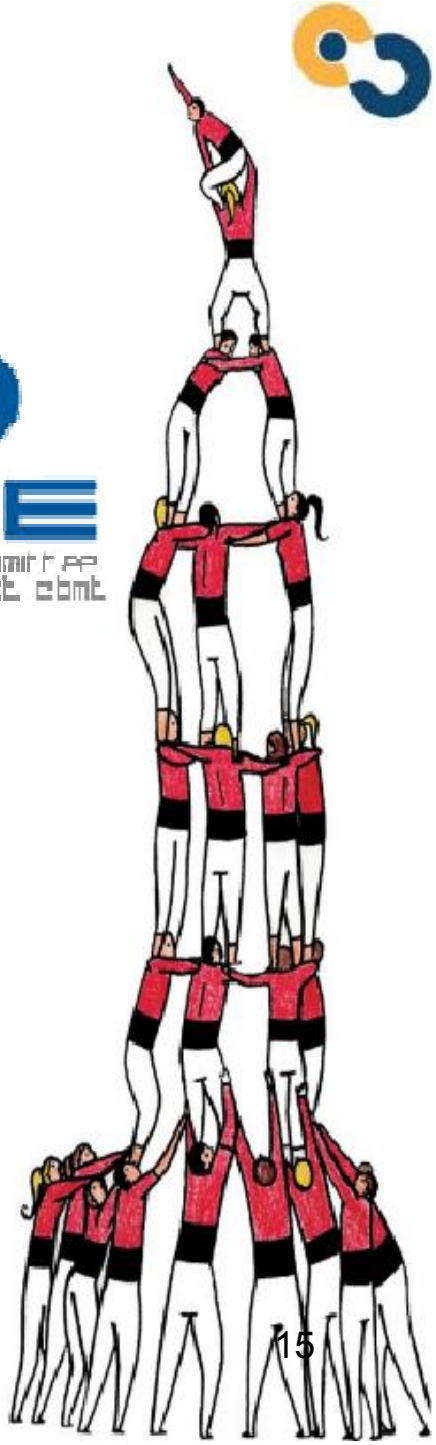
Application for Accreditation

1. GENERAL DETAILS





APPROVED

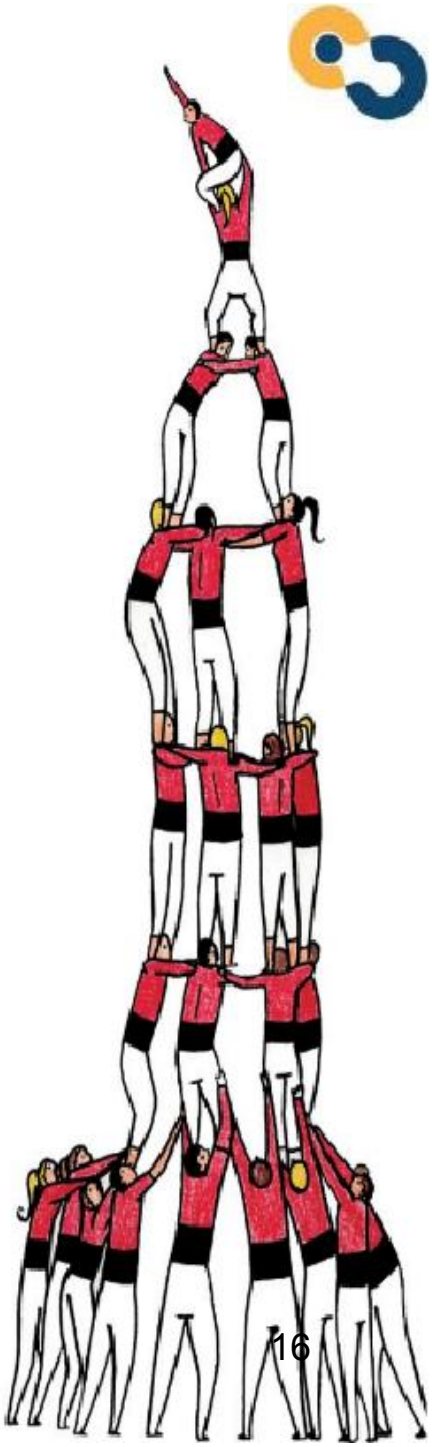


Inspection Checklist

Part B: Clinical

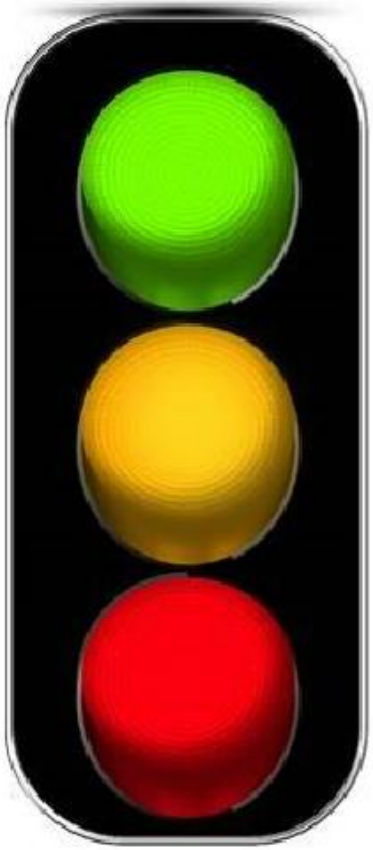
Ref.	Standard	Applicant's assessment	Source of evidence and explanatory text	Inspection: All items compliant? No	Inspector's Assessment	Inspector's Comments (support your answers with additional information)
B.01	GENERAL	BLANK CELL	BLANK CELL		BLANK CELL	BLANK CELL
B.01.01	The Clinical Program shall consist of an integrated medical team that includes a Clinical Program Director(s) located in a defined location(s).	Compliant	No evidence			
B.01.01.01	The Clinical Program shall demonstrate common staff training, protocols, procedures, quality management systems, clinical outcome analysis, and regular interaction among all clinical sites.	Partially compliant	No evidence			
B.01.02	The Clinical Program shall use cell collection and processing facilities that meet FACT-JACIE Standards with respect to their interactions with the Clinical Program.	Non-compliant	No evidence			
B.01.03	The Clinical Program shall adhere to all applicable laws and regulations.	Compliant	No evidence			
B.01.03.01	The Clinical Program shall be licensed, registered, or accredited as required by the appropriate governmental authorities for the activities.	Compliant	No evidence			
B.01.04	The Clinical Program shall have a designated transplant team that includes a Clinical Program Director, a Quality Manager, and a minimum of one (1) additional attending transplant physician. The designated transplant team	Compliant	No evidence			

Part B Clinical | B-CM-C 6 Donors | Part CN Bone Marrow



Inspection Checklist

- Based on Traffic Light system
  - Compliant
  - Partially Compliant
  - Non-compliant
  - Not Applicable (N/A)



Part B: Clinical

Inspector: All items compliant? No

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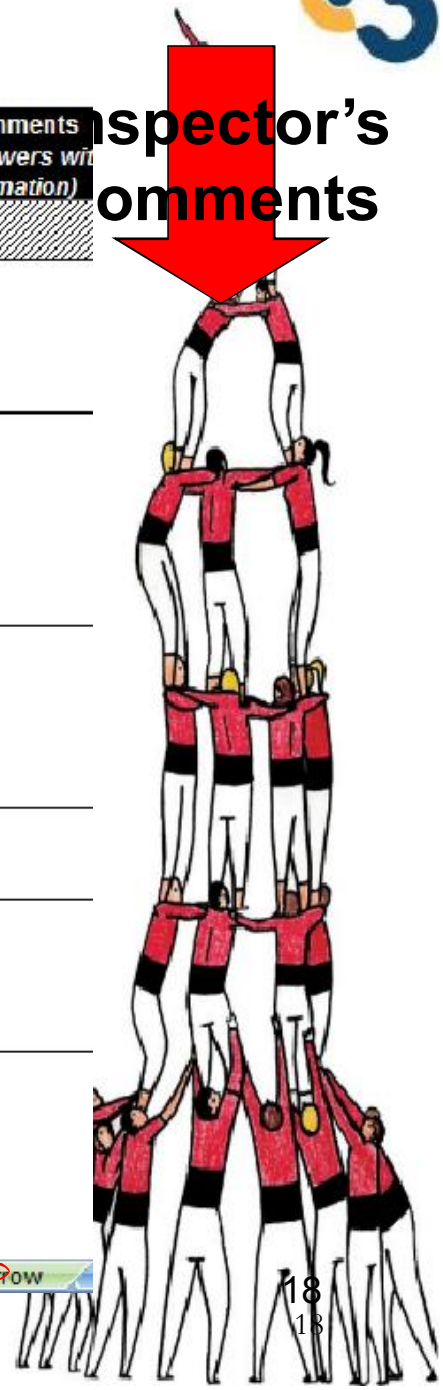
Snapshot | Dashboard | Part B Clinical | Part B MED-A audit forms | B-CM-C 6 Donors | Part CM Bone Marrow

Inspector's Comments



Submit documentation before inspection

- 3 months to submit documentation
- Language of the centre
- Labels
- Quality Manual
- List of SOPs
- Donor / patient consent information
- Evidence of qualifications
- Evidence of audits performed….

The Inspection Team

How does JACIE assign Inspectors?

- List of inspectors and indicate if any are **not** acceptable
- Where available, the National Representative is also involved at this point

Conflicts of Interest

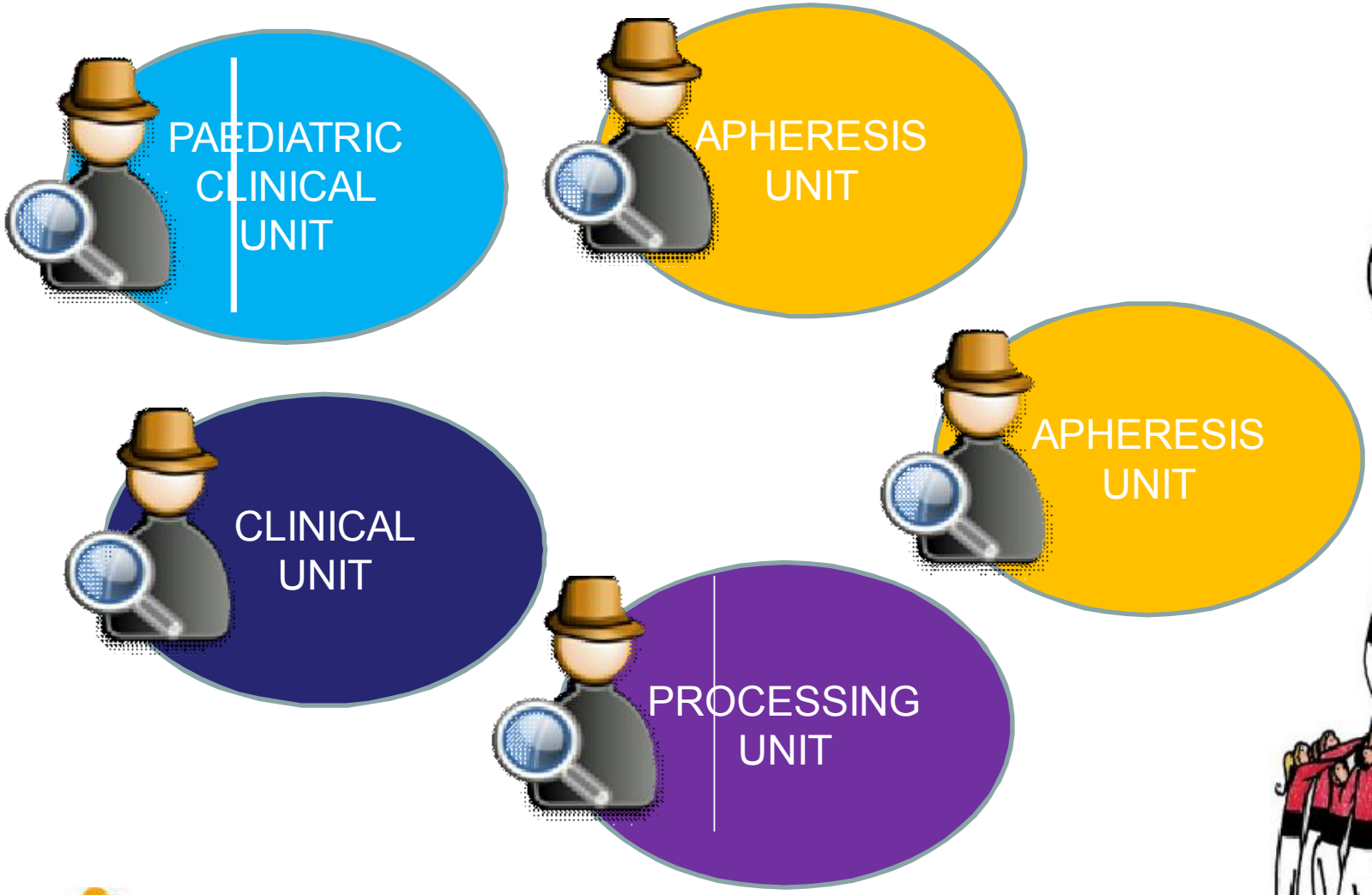
- Inspector and Centre must advise of any potential conflicts of interest, such as:
  - Previously worked in the centre
  - Will be working in that centre
  - Has directly assisted centre with preparations

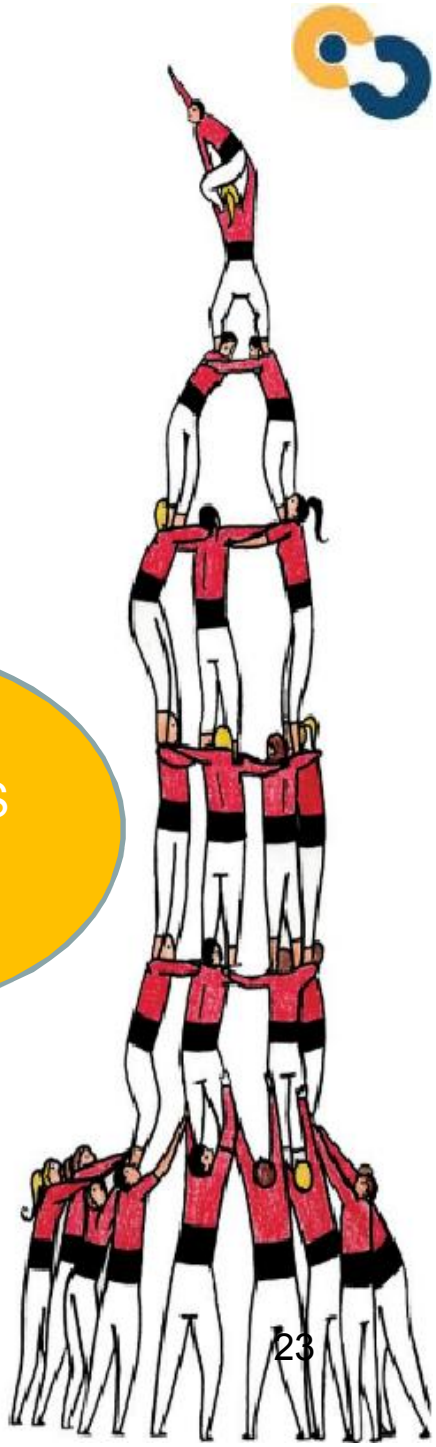
The Inspection Team

Inspectors then assigned on the basis of:

- Area of expertise
  - Clinical (Adult and/or Paediatric) / Collection / Processing
- Language skills
- Country
- City
- Availability!
- Non-reciprocal visits

Inspection Team





Inspection Team

- 1 team leader

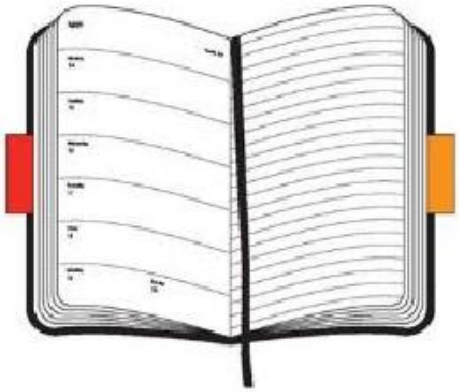
In addition, possible inclusion of:

- Observer e.g. JACIE National Representative, regulatory agency
- Trainee

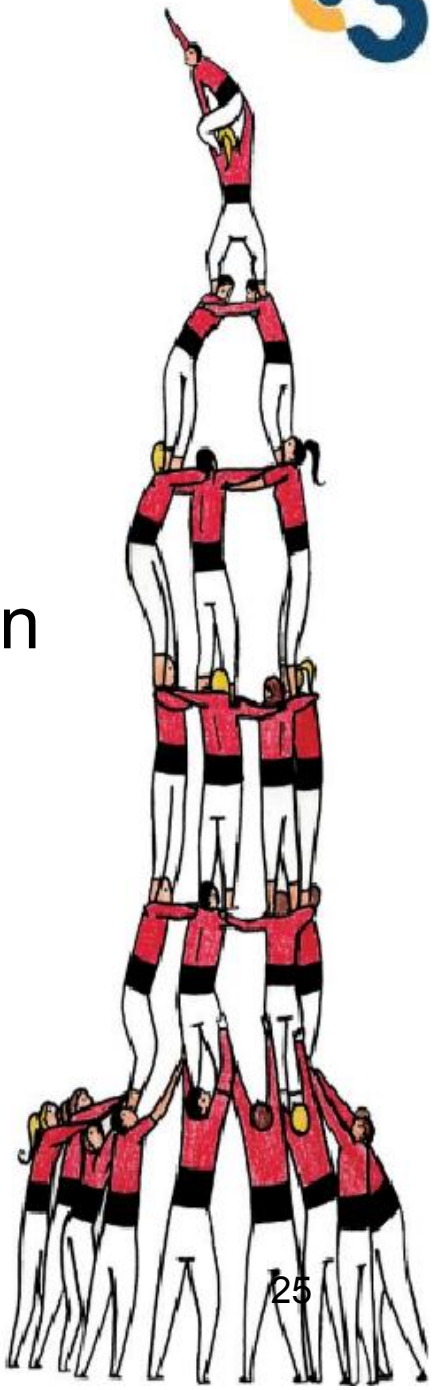
Team Leader

- Usually Clinician

- Point of contact between Team, Centre and JACIE Office

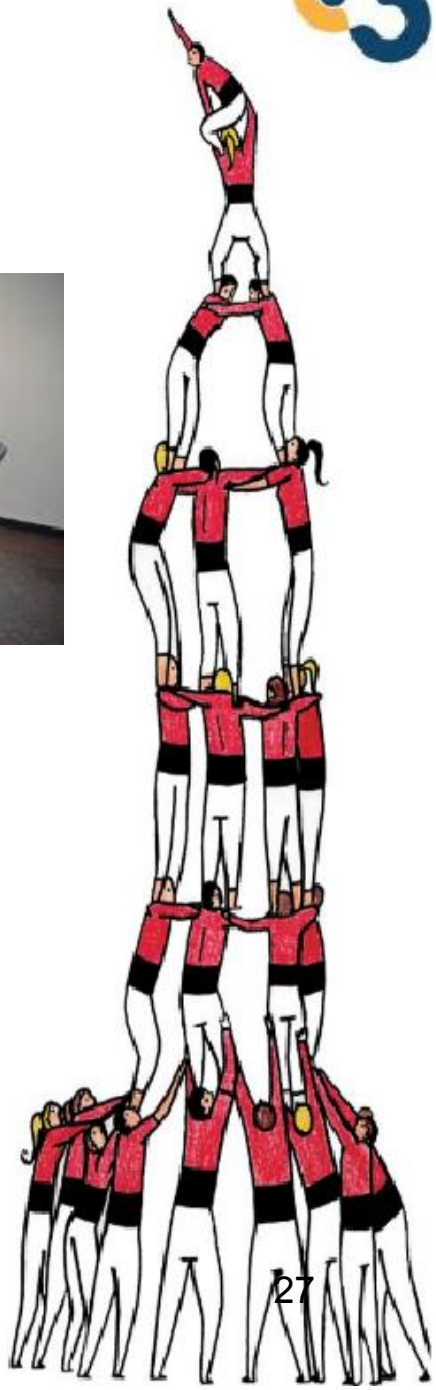


- Arranges timetable with programme director

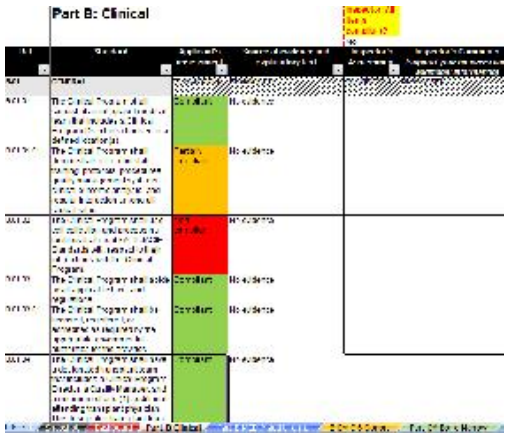


Inspection: Preparation

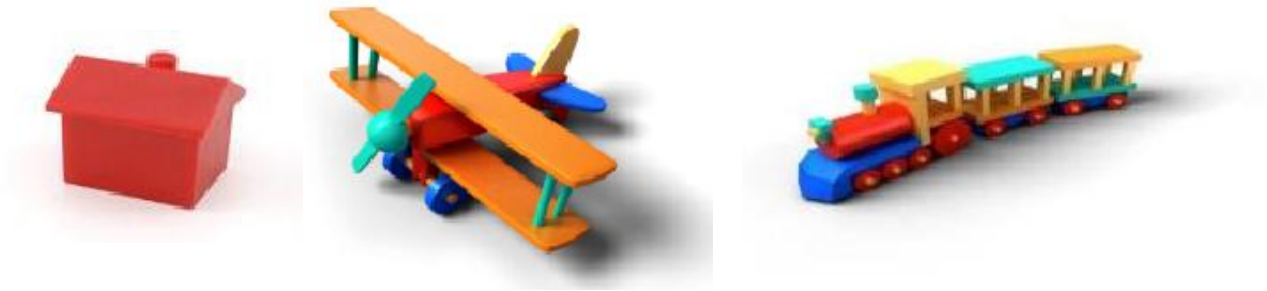
Applicant: Preparation



Inspector: Preparation



Travel & Hotel



- Inspectors make travel arrangements with JACIE Travel Agency
  - No big payments in advance for the inspector - JACIE pays directly
  - *Per diem* allowance €80

- Thank you for listening
- Any questions?