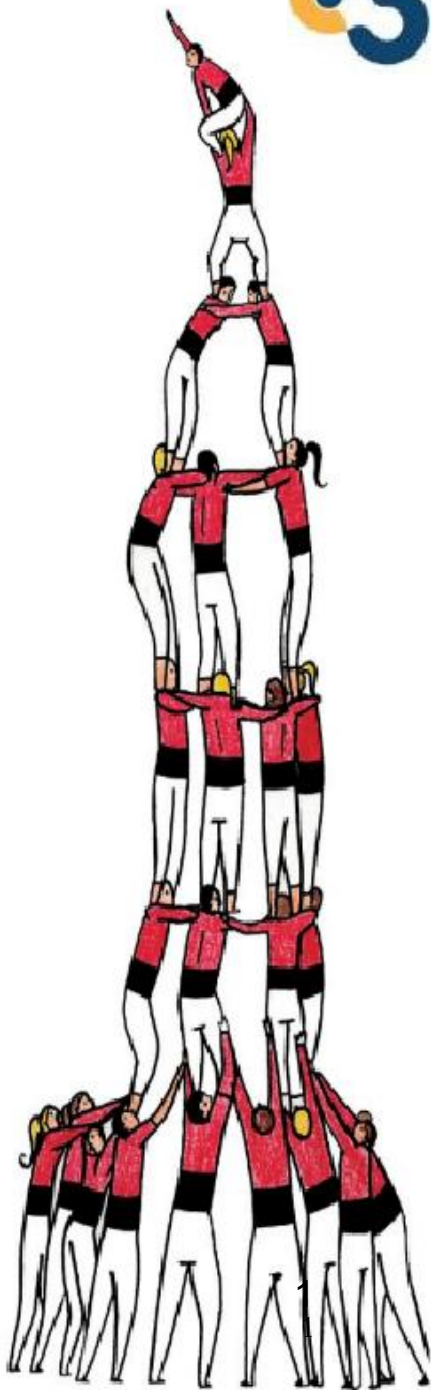
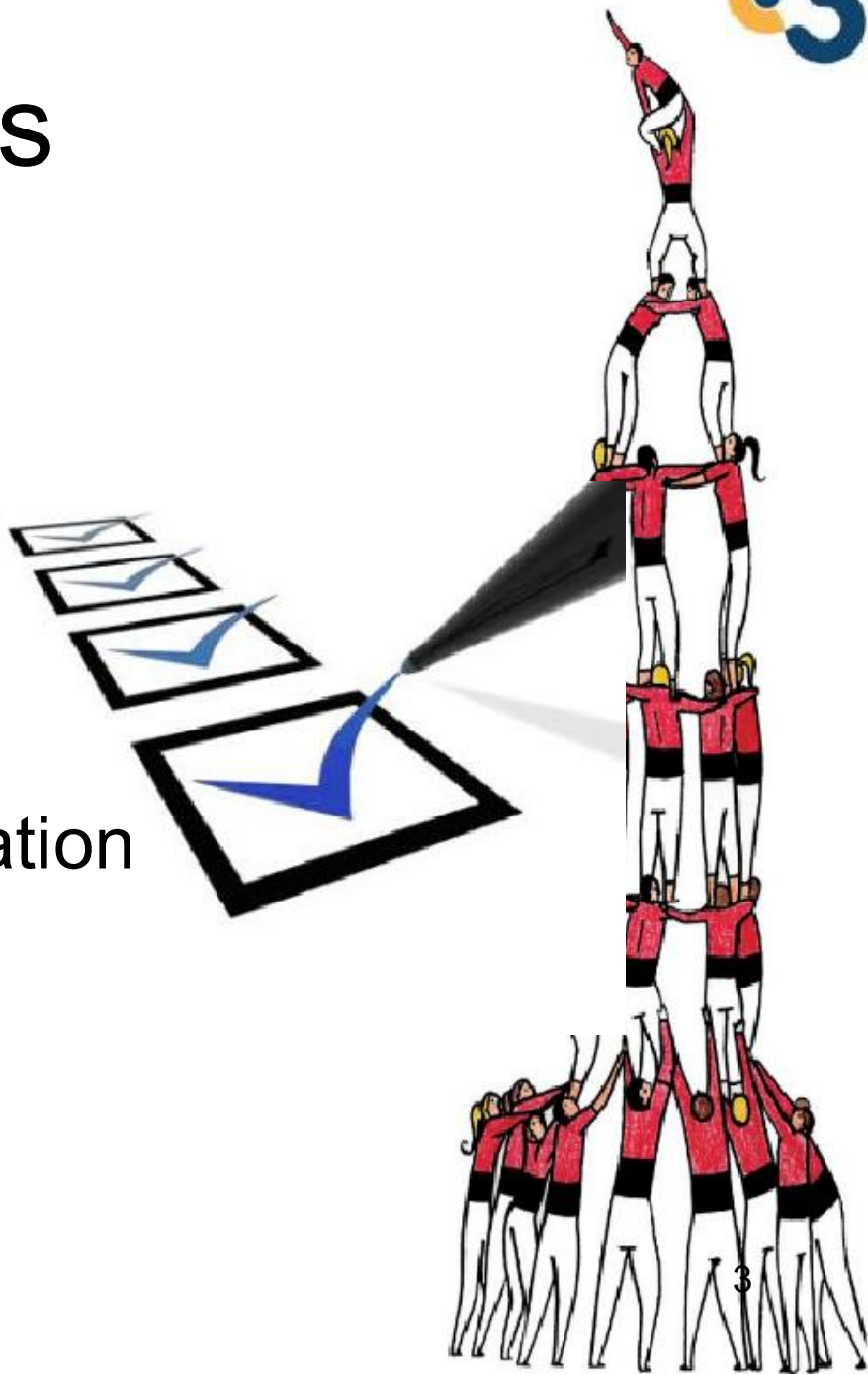
The JACIE Accreditation Process

JACIE Office,
Barcelona, Spain

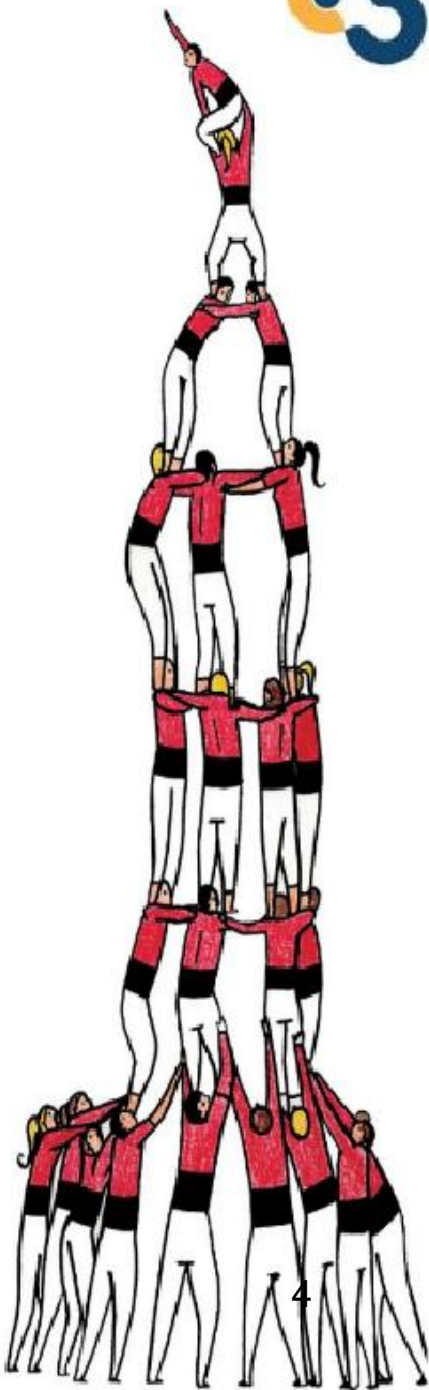


Contents

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



Phases



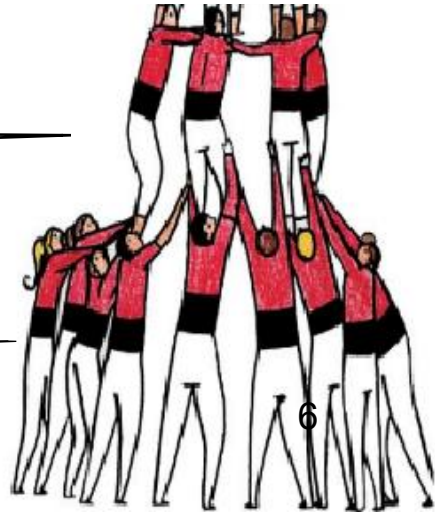
Process

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

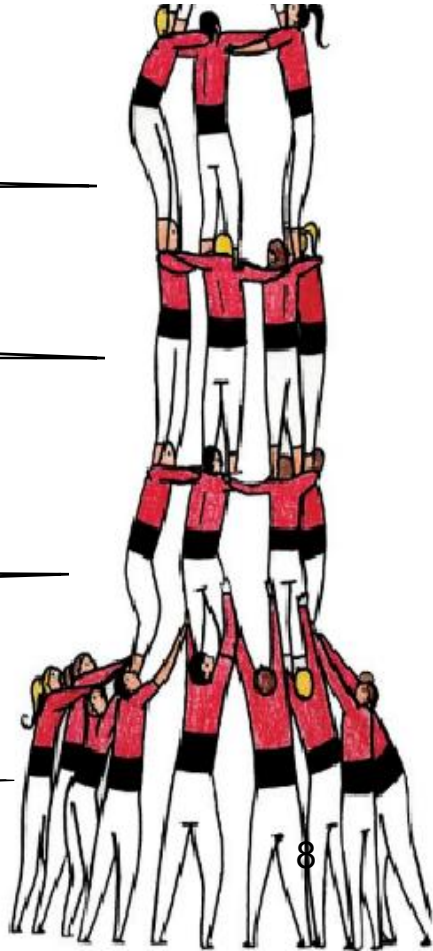
Process

Inspection

Request inspection

Preparations, working with quality

Decision to work according to the Standards



Process

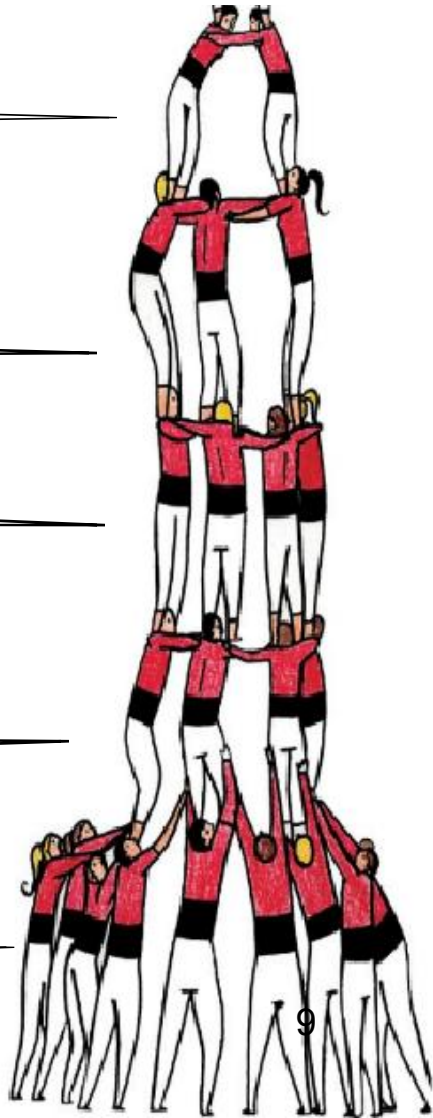
Corrections

Inspection

Request inspection

Preparations, working with quality

Decision to work according to the Standards



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Accreditation

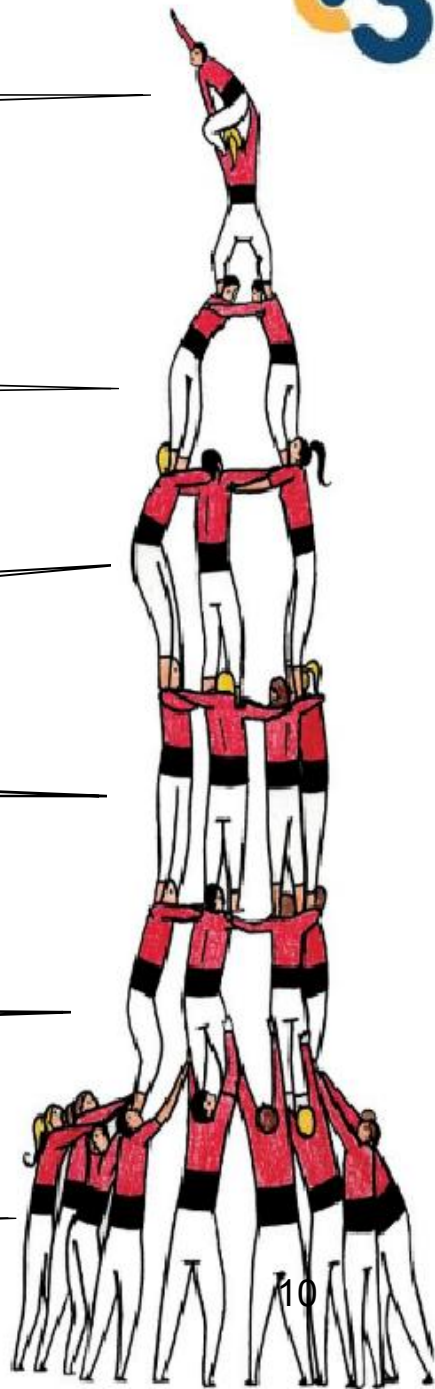
Corrections

Inspection

Request inspection

Preparations, working with quality

Decision to work according to the Standards



Keep going!

AFTER

Accreditation

Make changes

Inspection

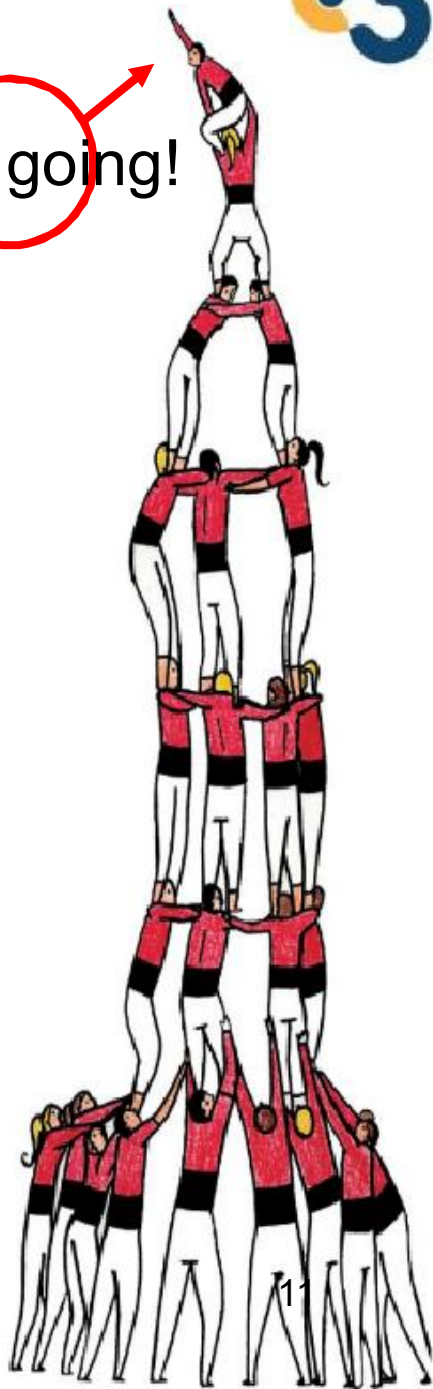
Apply

Self-check

BEFORE

Preparation

Decision



Preparation by the centre

- Create a Quality Management Group

- Write QM, SOPs Instructions

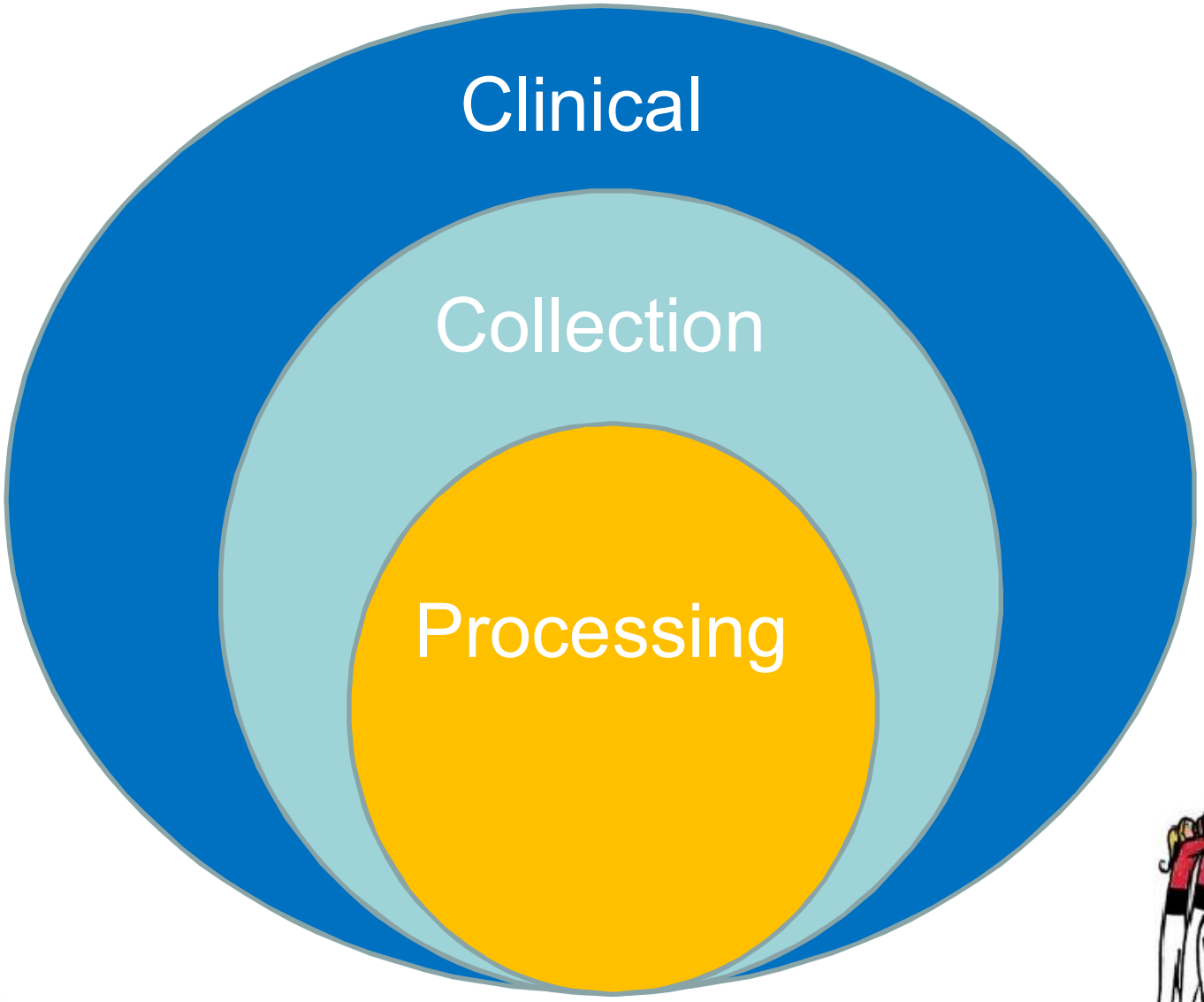
- Establish Indicators

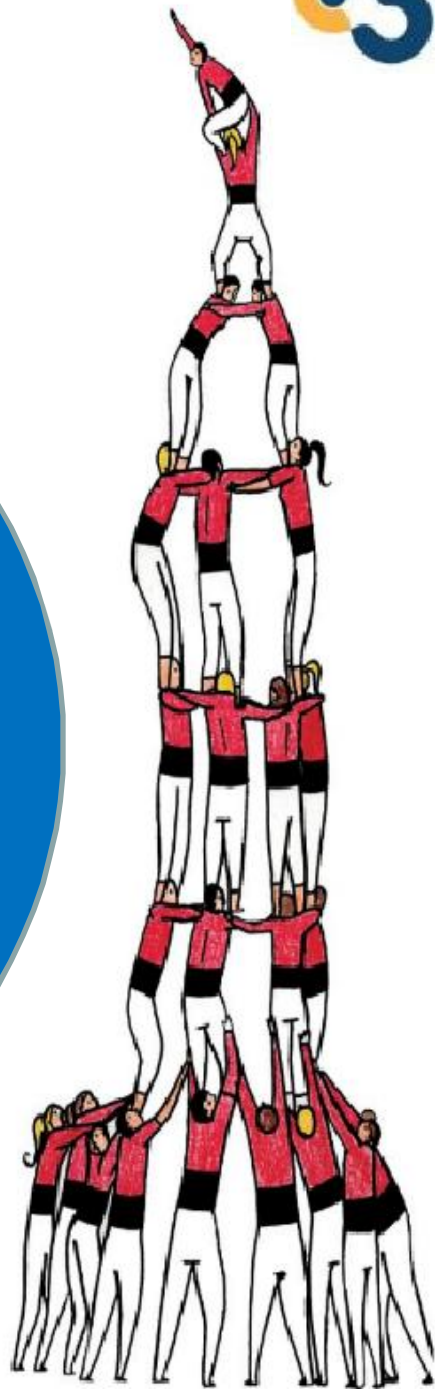
- Perform Audits

- Document Training

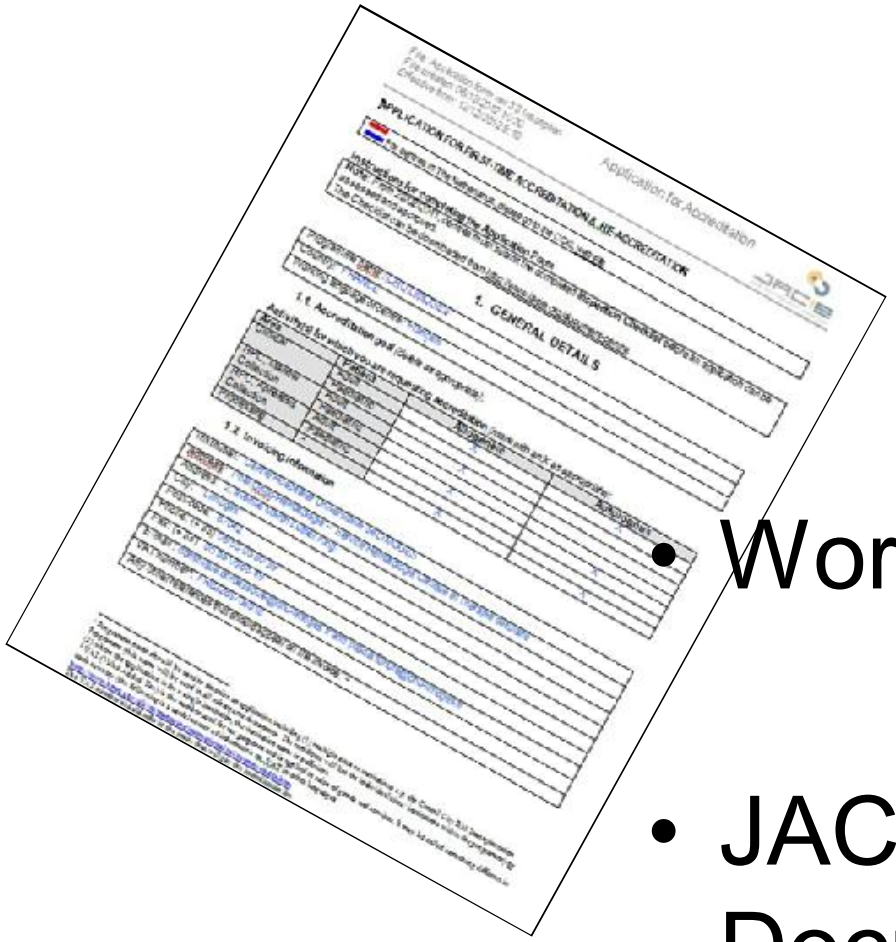
Remember to provide evidence

Accreditation

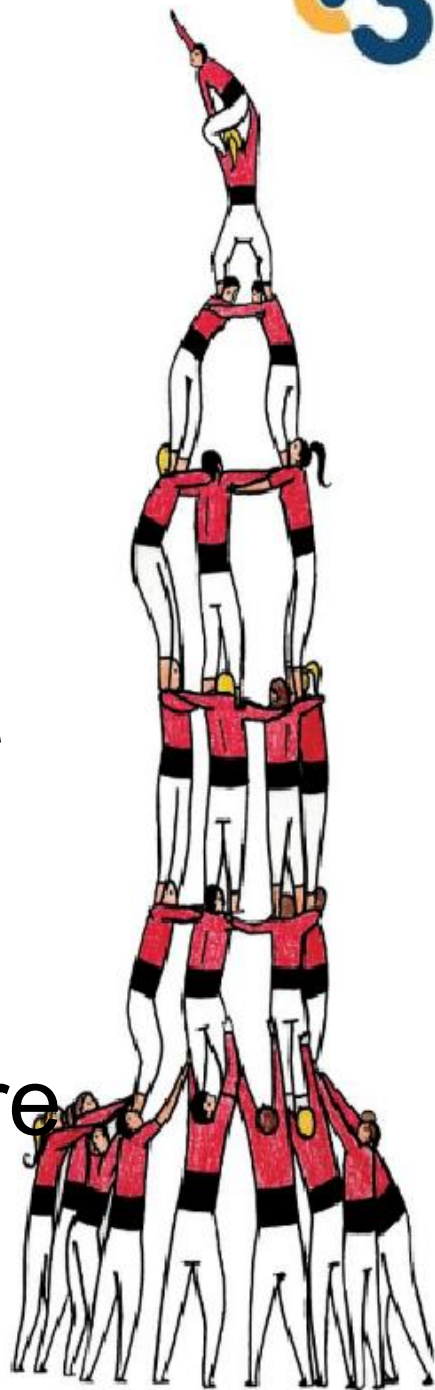


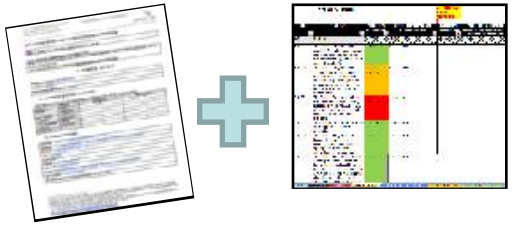


Application Form



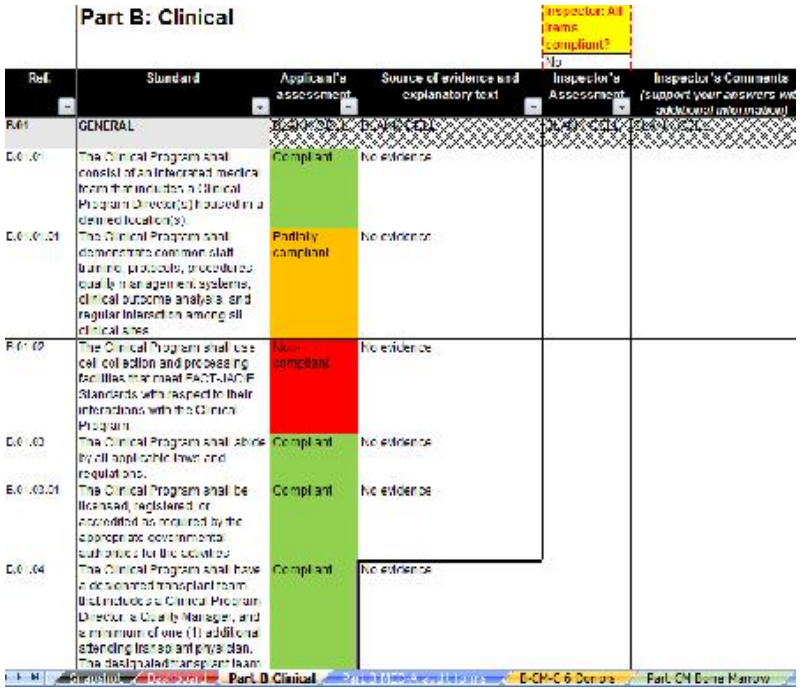
- Word Document
- JACIE Website/ Document Centre






APPROVED

Inspection Checklist



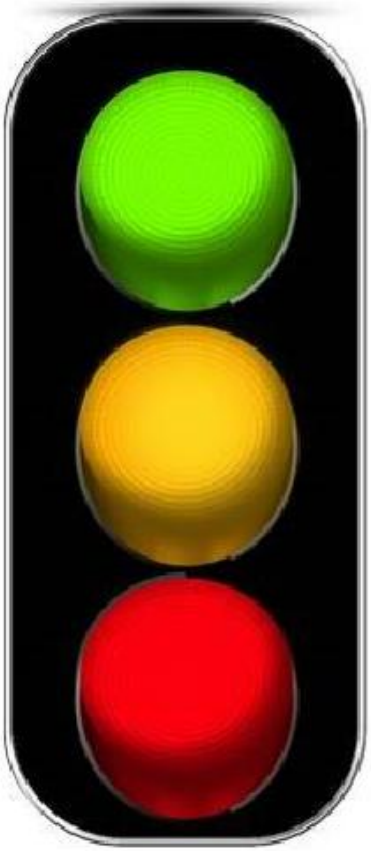
Part B: Clinical

Ref.	Standard	Applicant's assessment	Source of evidence and explanatory text	Inspector's Assessment	Inspector's Comments (support your answers with additional information)
B.01	GENERAL				
B.01.01	The Clinical Program shall consist of an integrated medical team that includes a Clinical Program Director(s) housed 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 abide by 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 | D-CH-C 6 Donors | Part C N Bone Marrow

Inspection Checklist

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



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Part B: Clinical

Inspector: All items compliant?
No

Ref.	Standard	Applicant's assessment	Source of evidence and explanatory text	Inspector's Assessment	Inspector's Comments *(support your answers wit 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) housed in a defined location(s).	Compliant	No evidence		
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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		
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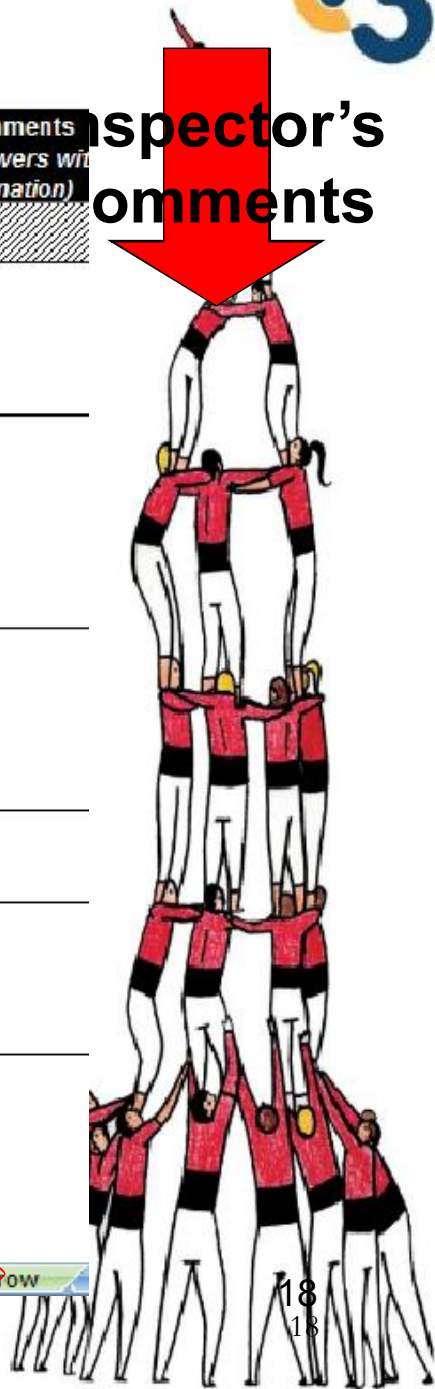
Snapshot | Dashboard | Part B Clinical | Part B MED-A audit forms | B-CM-C 6 Donors | Part CM Bone Marrow

spector's
omments



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Accreditation Agreement

- Approval of application
- Quotation
- 2 Weeks to submit the JACIE Accreditation Agreement Signed

Submit documentation before inspection

- 30 days to submit documentation
- Labels
- List of SOPs
- Donor / patient consent information
- Evidence of audits performed….

Documentation in the language of the Centre

Inspection Team

PAEDIATRIC CLINICAL UNIT

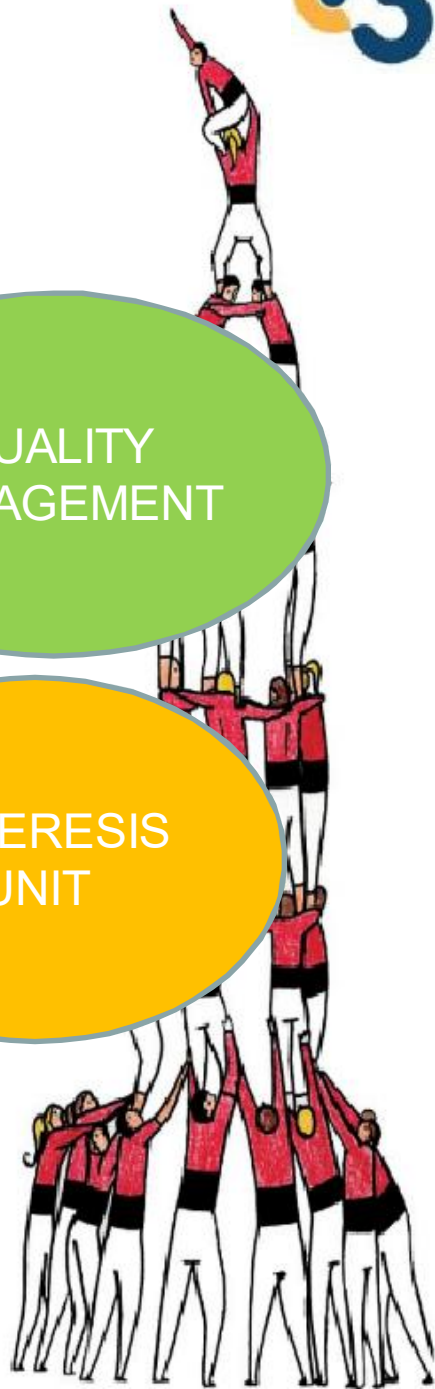
APHERESIS UNIT

QUALITY MANAGEMENT

CLINICAL UNIT

APHERESIS UNIT

PROCESSING UNIT



Inspection Team

- Language of the centre
- Language facilitator can be added to the team

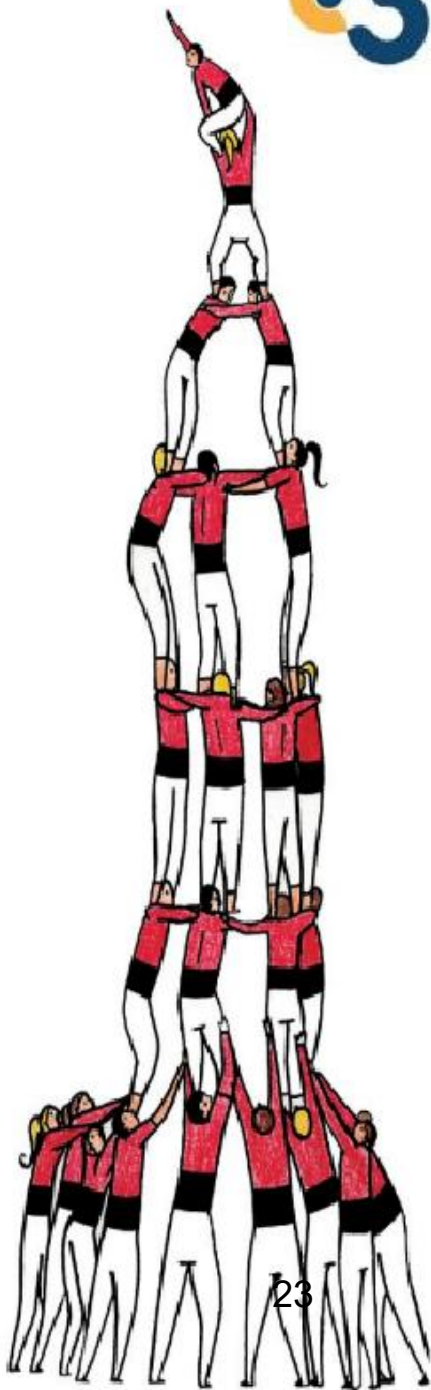
- Centre is invited to look at the JACIE list of inspectors, public in JACIE website
- Centre & Inspector shall inform of potential conflicts of interest

Inspection Team

- 1 team leader

In addition, possible inclusion of:

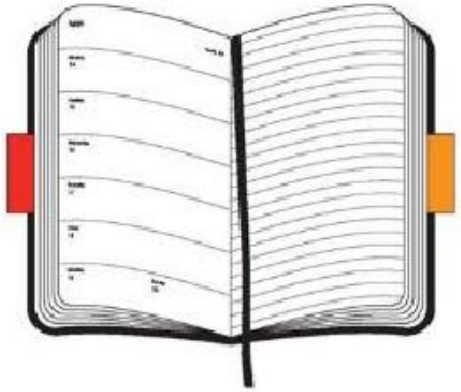
  - Observer e.g. JACIE National Representative, regulatory agency
  - Trainee



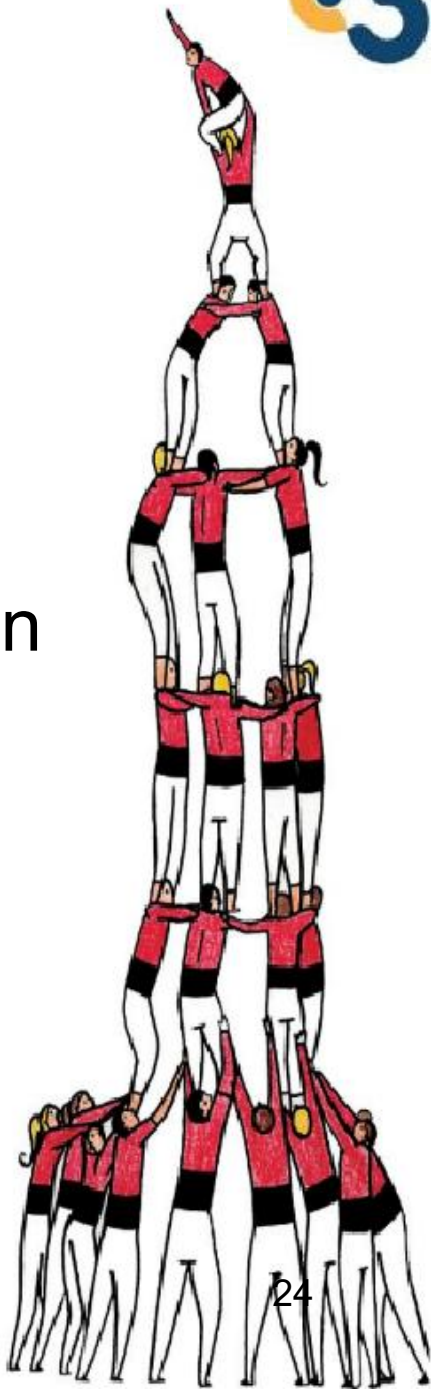
Team Leader

- Usually Clinician

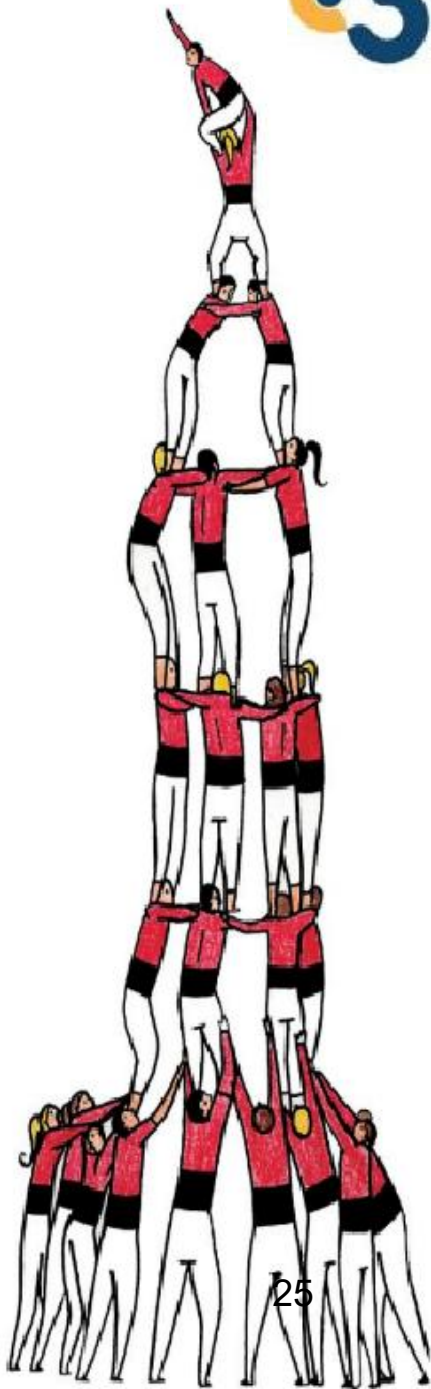
- Point of contact between Team, Centre and JACIE Office



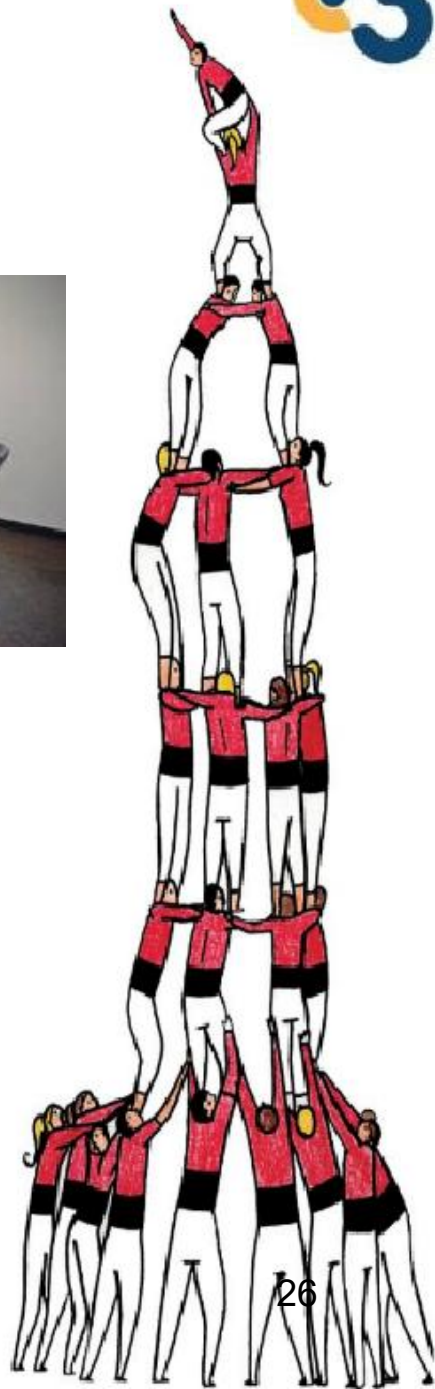
- Arranges timetable with programme director



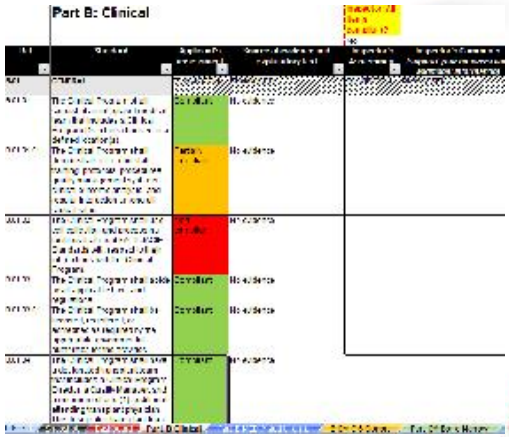
Inspection: Preparation



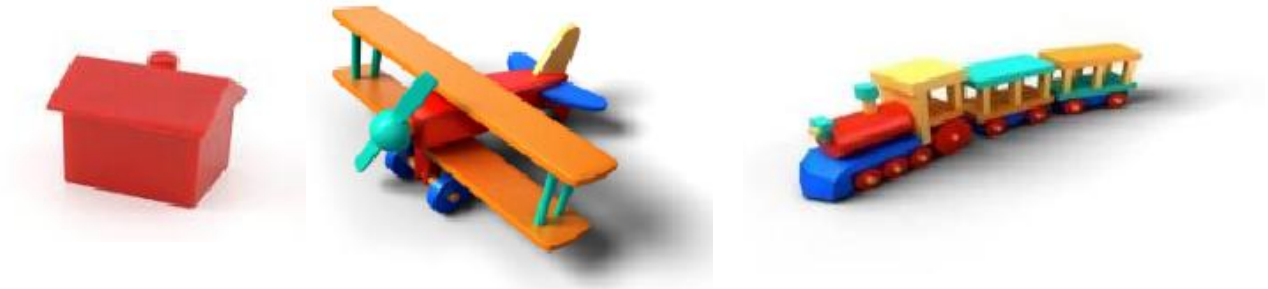
Applicant: Preparation



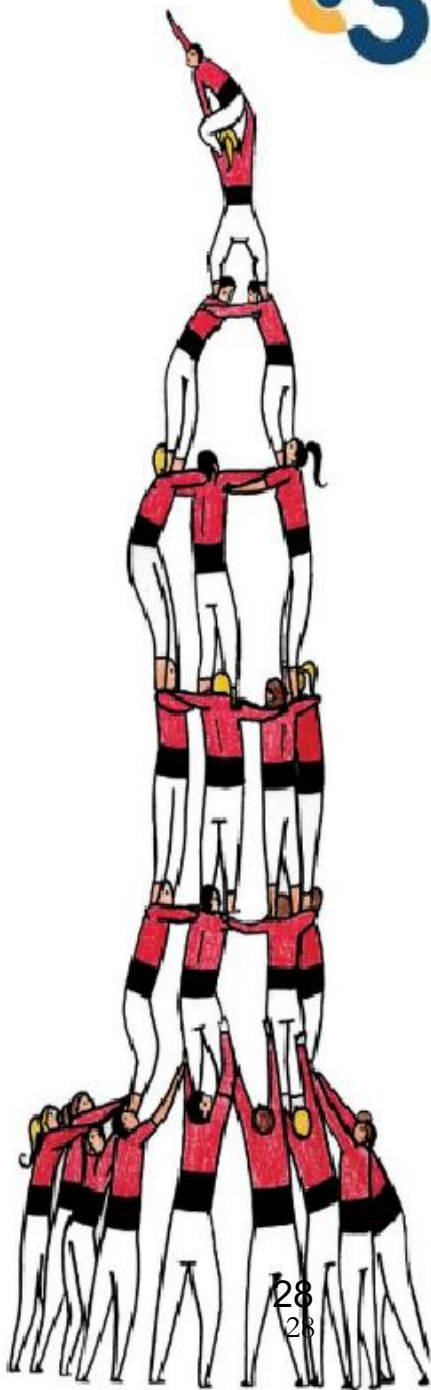
Inspector: Preparation



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



Time-Line

Application

JACIE Agreement Signed

Pre-audit documentation Submission

Inspection

Approval Quotation JACIE Agreement

Invitation

Teleconference

~1/2 weeks

2 weeks

1 month

~6 months

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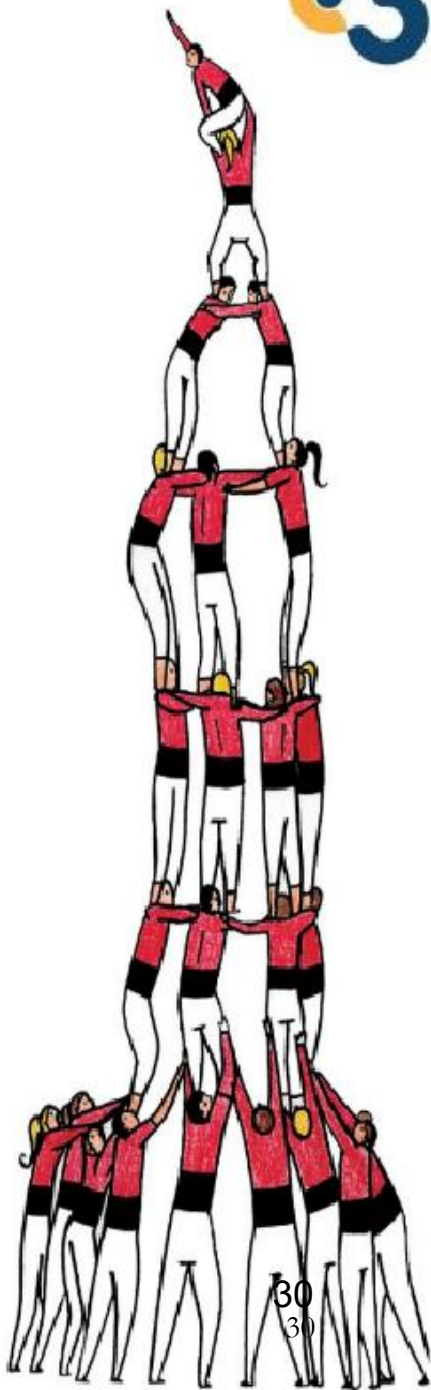
- Thank you for listening
- Any questions?



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