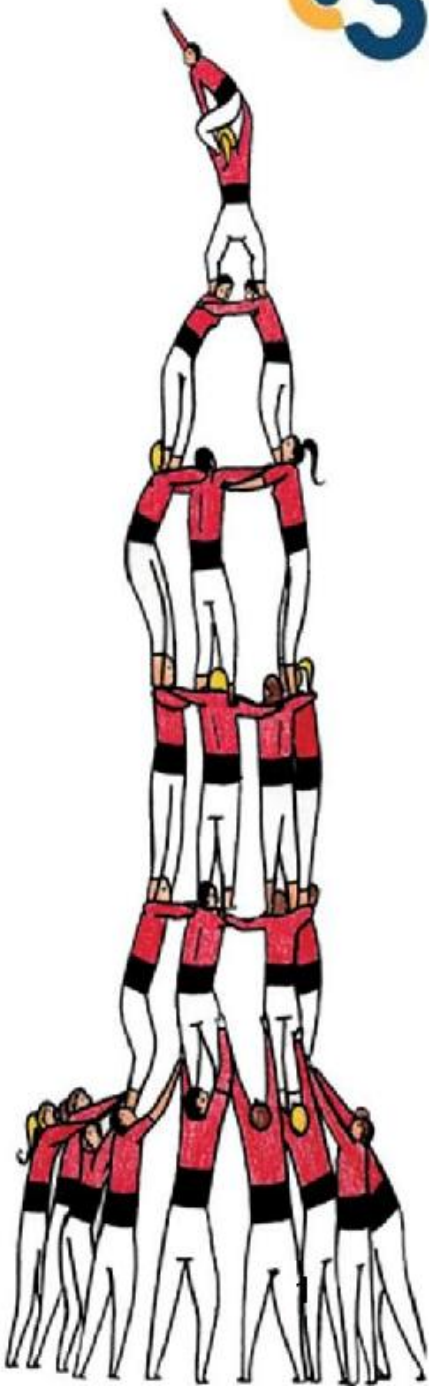
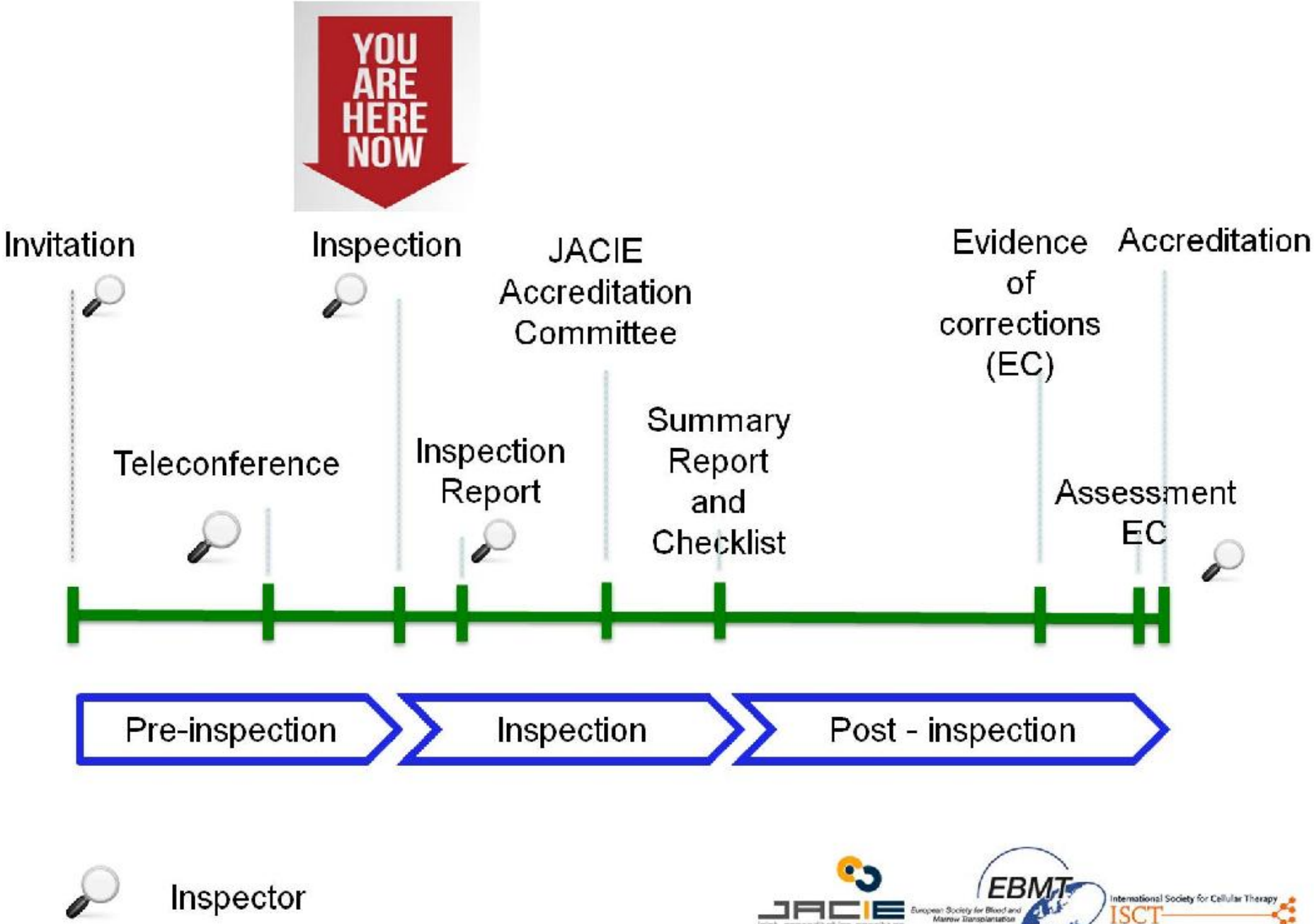
The JACIE Accreditation Process

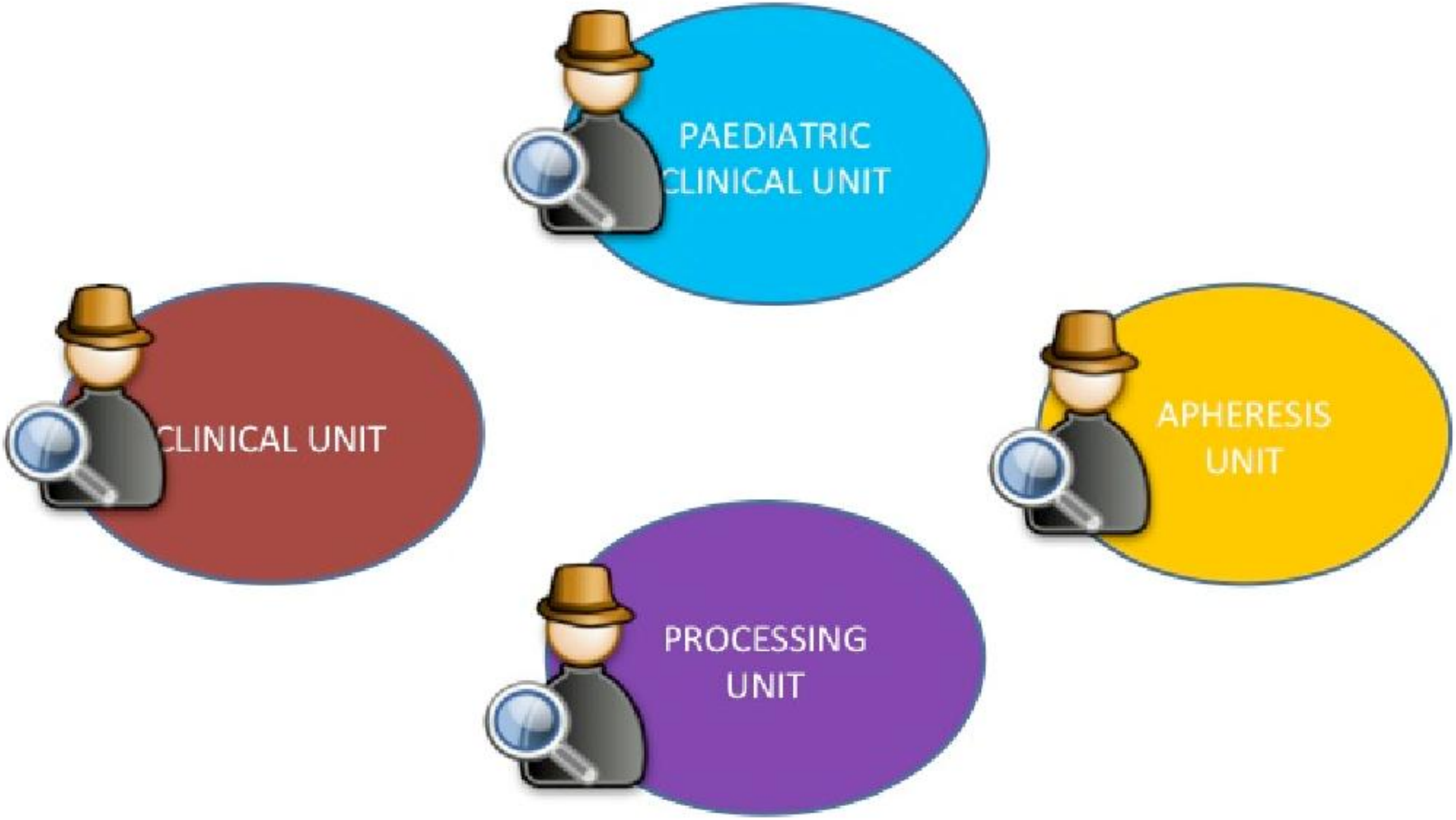


JACIE Office,

Barcelona, Spain


YOU ARE HERE NOW
Invitation
Inspection
JACIE Accreditation Committee
Evidence of corrections (EC)
Accreditation
Teleconference
Inspection Report
Summary Report and Checklist
Assessment EC
Pre-inspection
Inspection
Post - inspection
Inspector

Current Inspection Team

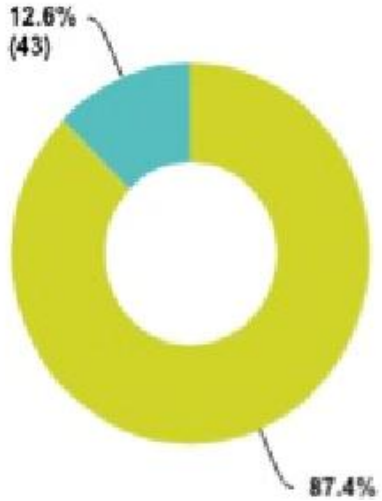


Creating Inspectors Role for Quality Management

Survey Sep-Oct 2014

Should a Quality Manager (QM) be incorporated into the Inspection Team subject to meeting established criteria?

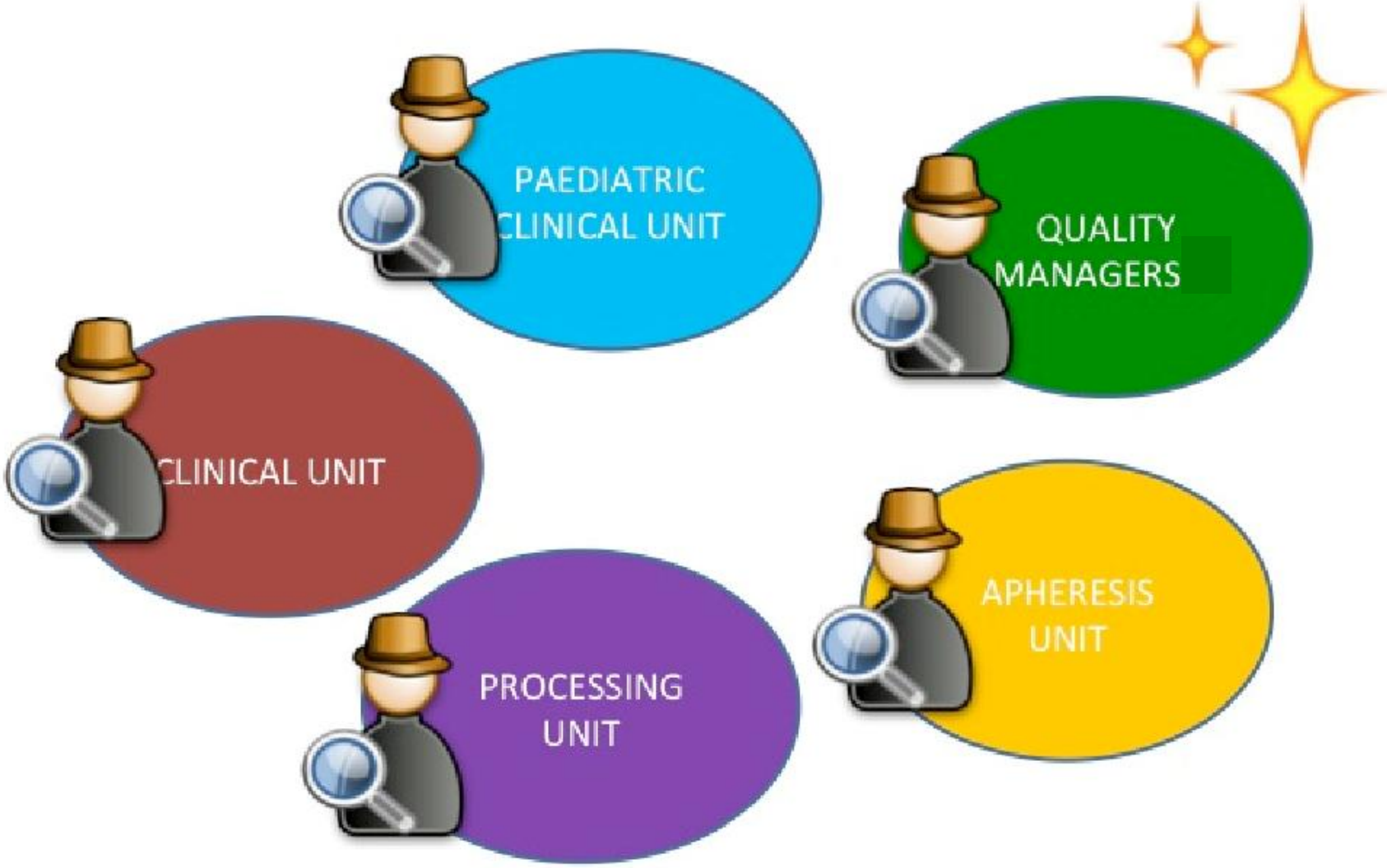
Answered: 340 Skipped: 0



Pilot test

Belgium
UK
Italy
Germany

Pilot Test Inspection Team



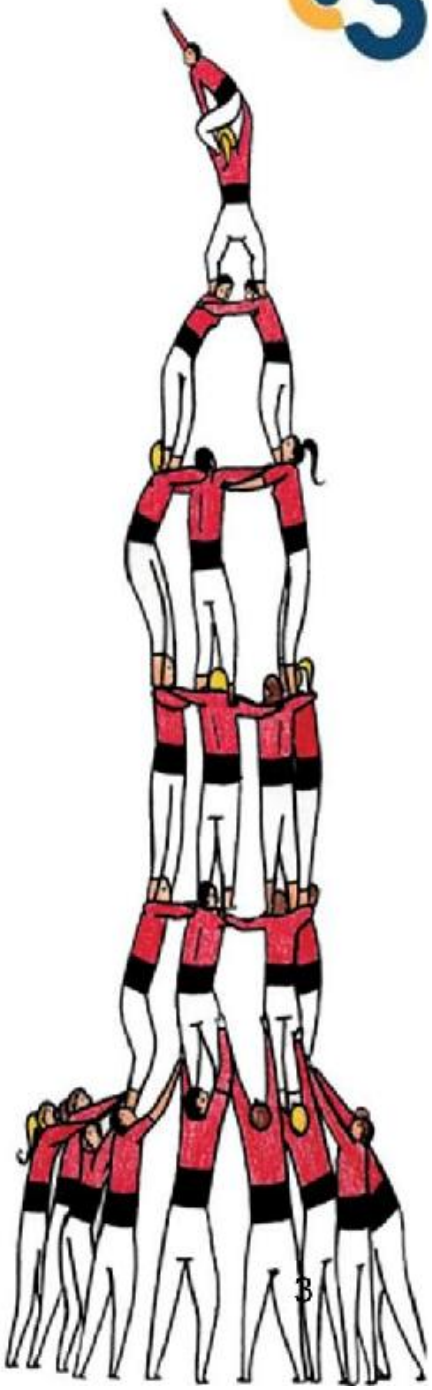
Quality Manager Inspector

QM Inspector Responsibility

- Parts B/CM/C/D 4 QM excluding:
  i. Outcome analysis
  ii. Tracking & traceability / labeling requirements
  iii. Qualification
  iv. Validation
- Parts B/CM/C/D 5 Polices & Procedures
- Part B9 Data Management

Inspection timetable

- Usually 1.5 days
  - Depending on scope of inspection, could also be 1 or 2 days
- Proposal made by Team Leader
- Reviewed by the centre <u>who can insist on reasonable changes if necessary</u>



Sample timetable

1st Half-day Period

Inspectors' arrival to the site, introduction & presentation of overall clinical programme by Programme Director

MEDA/B data audit and initial review of documentation

Quality Manual & SOPs and documentation

2nd Half-day Period

Tour around facilities demonstrating links between facilities.

Interviews**

Clinical

Programme Director
A transplant physician
The quality manager
Senior Nurse
Nurse responsible for training
BMT unit nurses
Pharmacist

Cell Collection

Collection facility director
Collection facility medical director
Potentially any staff involved in collection of cells

Laboratory

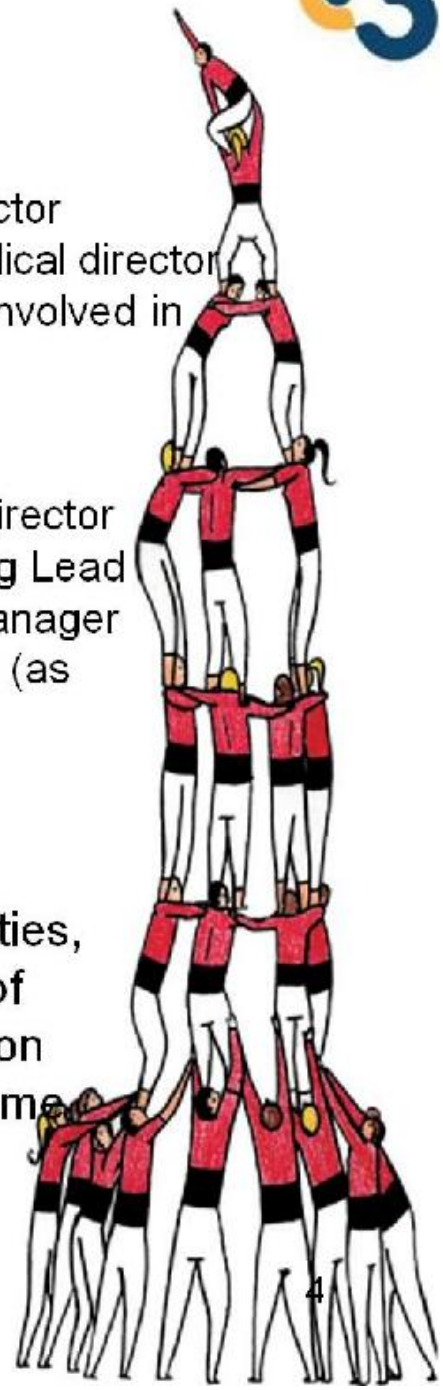
Laboratory Director
Laboratory Medical Director
Laboratory Processing Lead
Laboratory Quality Manager
Laboratory Trainee(s) (as appropriate)

3rd Half-day Period

Continue tour around facilities, interviews and review of remaining documentation

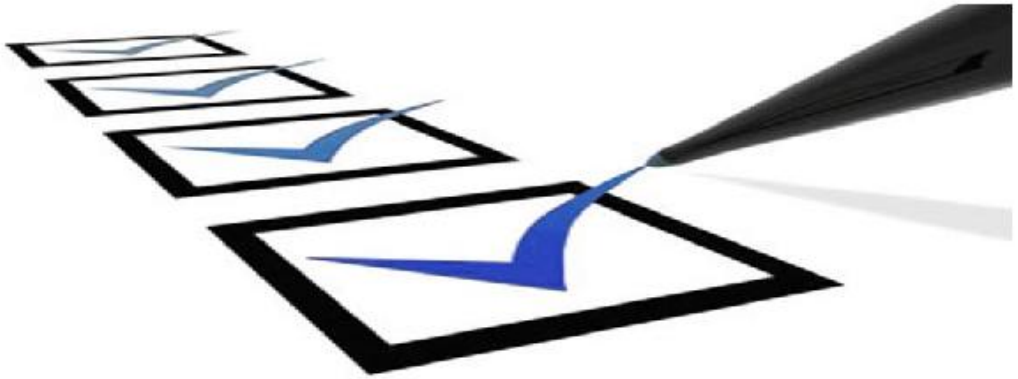
Exit Meeting with Programme Director.

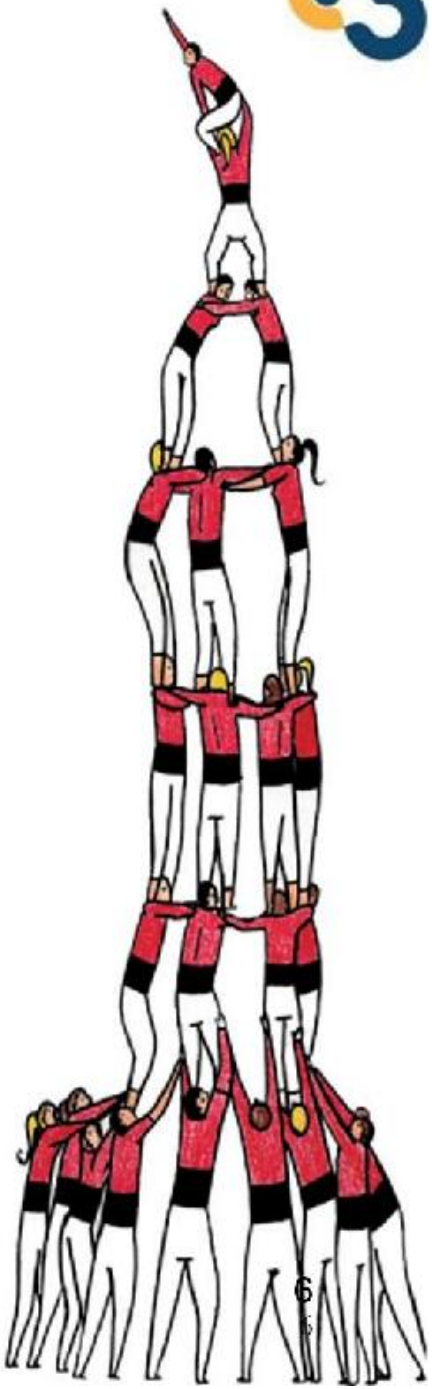
Closing Meeting



Inspection

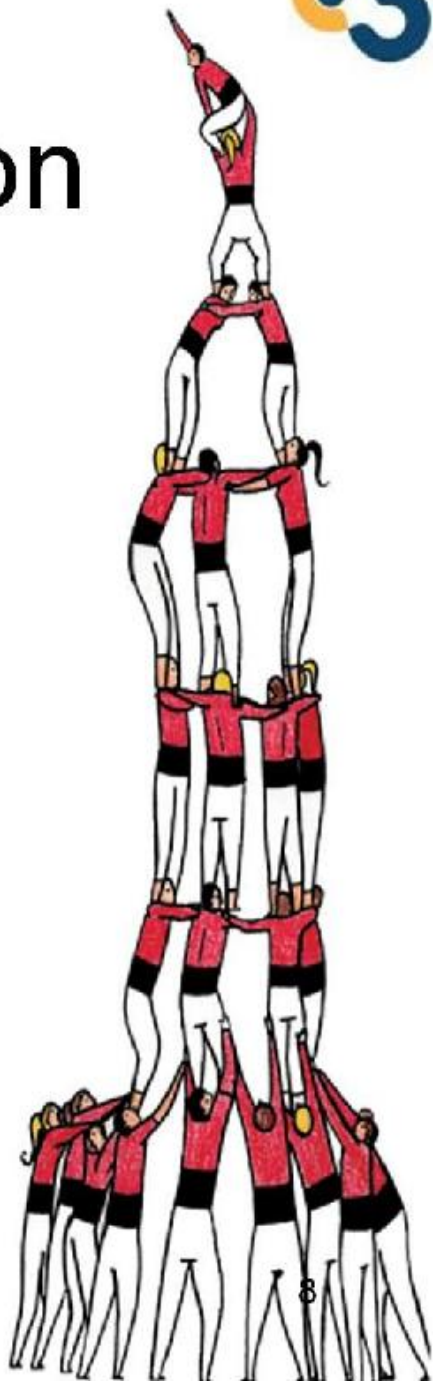
- Thorough examination of all aspects of the programme.
- Verification of the applicant's completed checklist



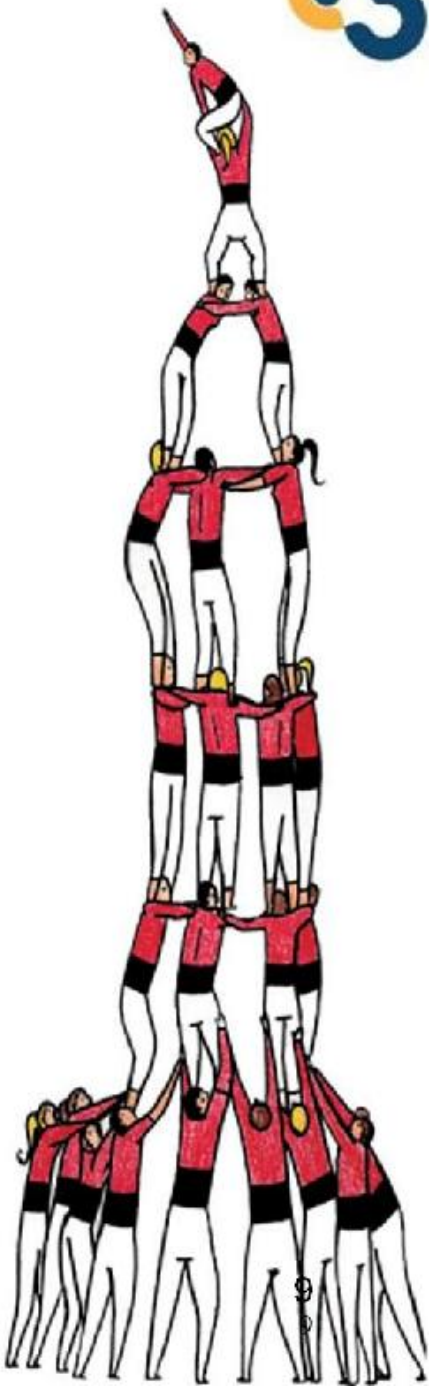


At the end of the inspection

- The exit interview
  - Inspector will discuss any sensitive issues with facility head and/or **Programme Director** in private BEFORE exit interview
  - The inspectors discuss their visit and inform the Programme Director and staff of what they found
  - Inspectors **do not** comment on possible outcome

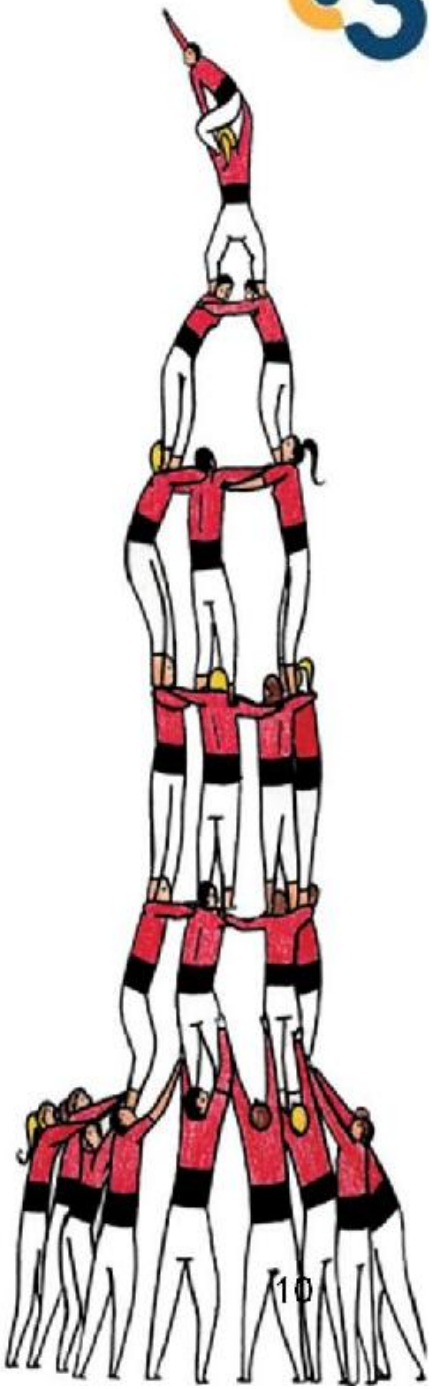


Post-inspection



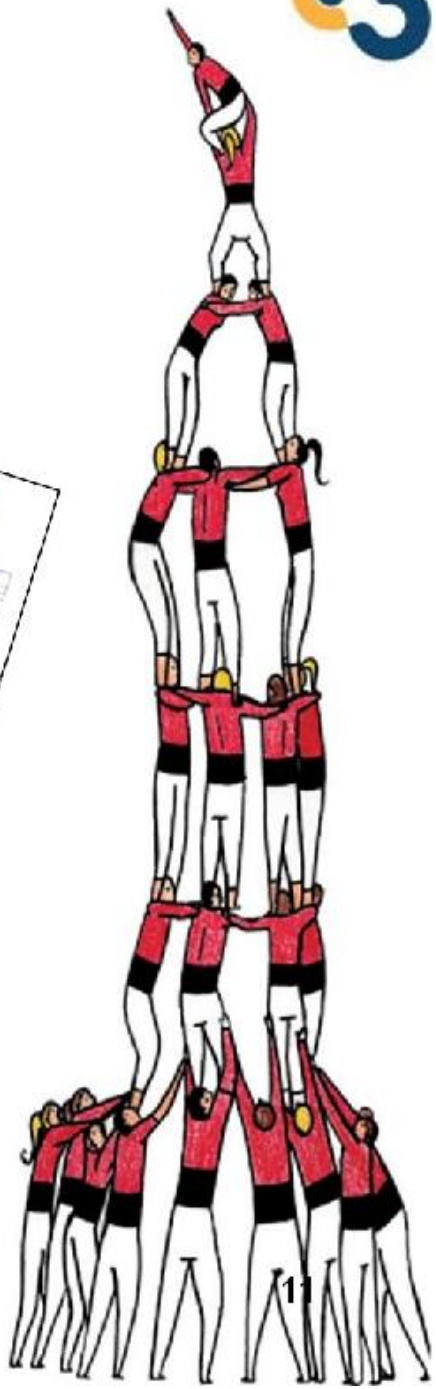
The Inspector

- Inspectors return Completed Inspection Checklist, any notes and documents to the Team Leader (TL) or directly to JACIE Office



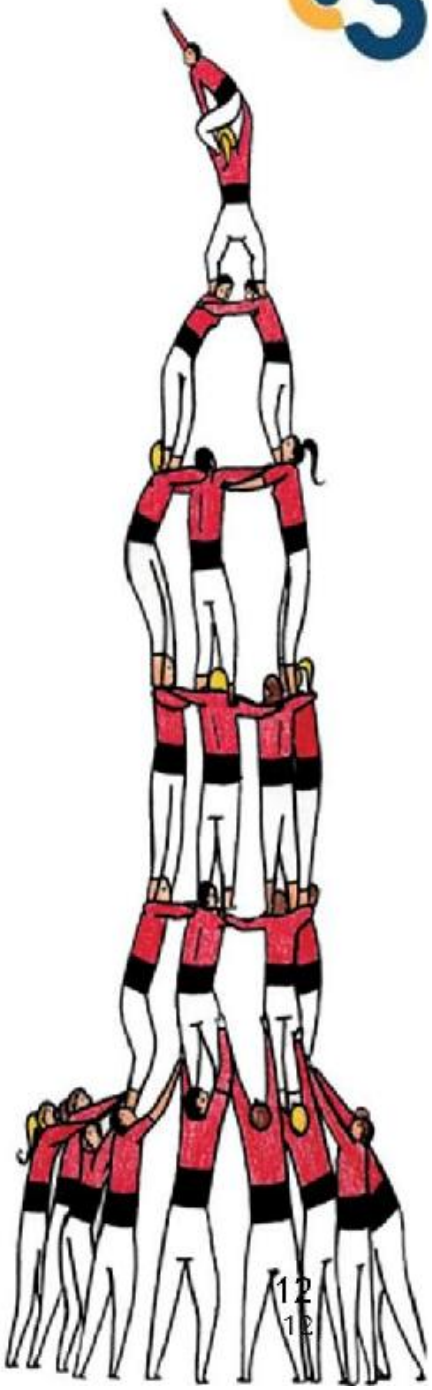
The Inspector

- TL compiles summary inspection report based on discussions with the other inspectors and their observations



The Applicant

- Complete and return the Onsite Evaluation form for JACIE Office
  - Opportunity to raise concerns (or give praise!) about anything involving the on-site inspection
  - Results sent to inspectors



Post-inspection evaluation

JACIE
joint accreditation committee
isct. ebmt

JACIE ON-SITE INSPECTION EVALUATION (Applicant)

This survey should be completed by centres that have recently undergone a JACIE inspection.
The information collected in this survey is confidential. Please use the survey to report your satisfaction or dissatisfaction with any aspects of the inspection or application process.
If you have any questions, please contact the JACIE Office at +34 93 453 8711 or jacie@ebmt.org.

*** 1. First name and Family name of person completing the survey**

*** 2. Position or role of person completing the survey**

- Service Director
- Quality Manager
- Nurse
- Data Manager
- Other

If other, please specify

*** 3. Name of applicant centre/programme**

*** 4. City**

*** 5. Country**

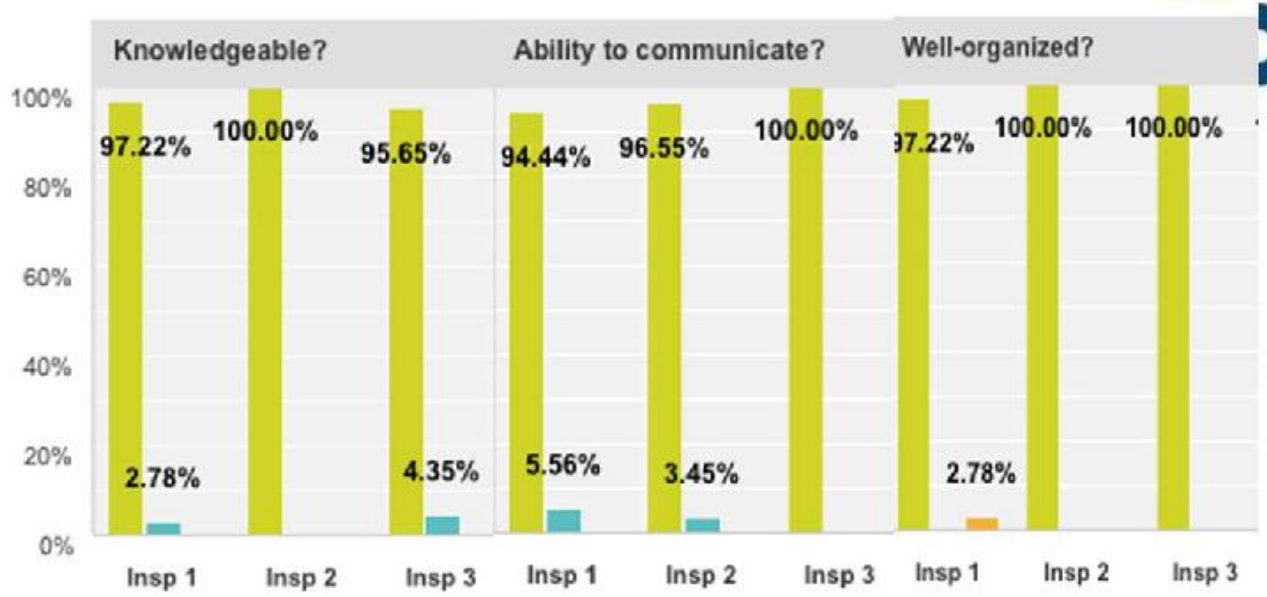
*** 6. Date(s) Of Inspection**

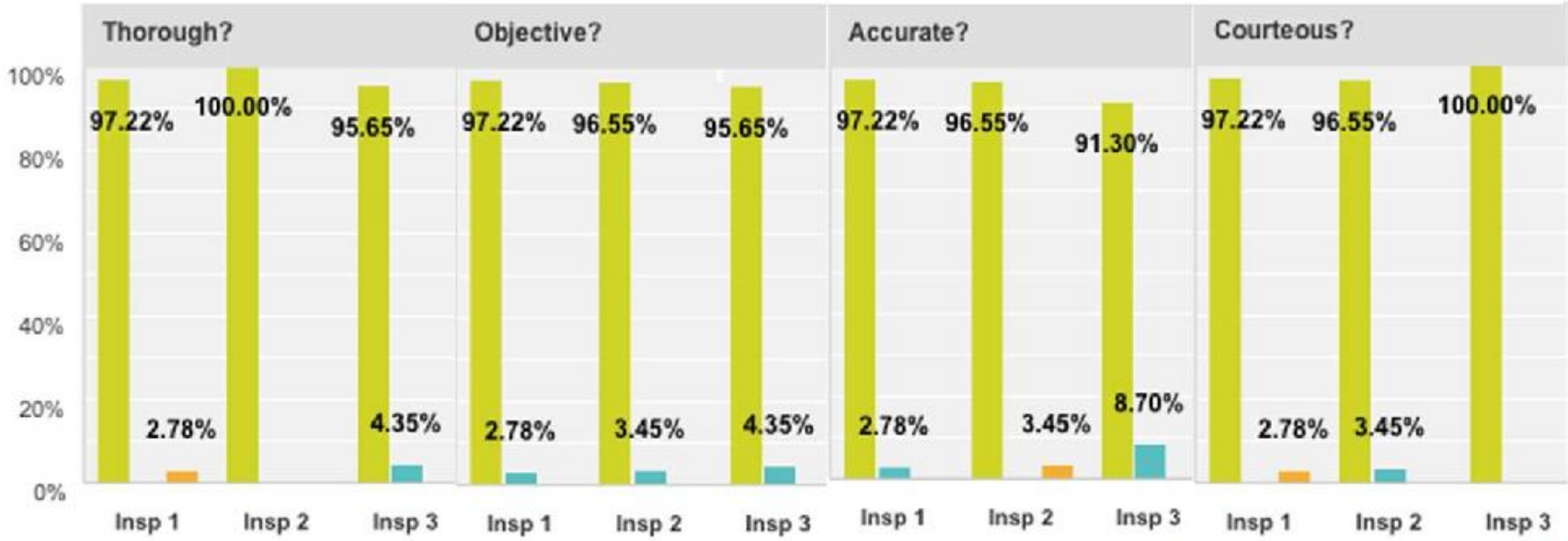
DD MM YYYY

Applicants Feedback + Inspectors Feedback = Improvement of the Accreditation Process

Applicant:
Please assess the followi
aspects of the inspector's
performance

Satisfactory
Unsatisfactory
No comment

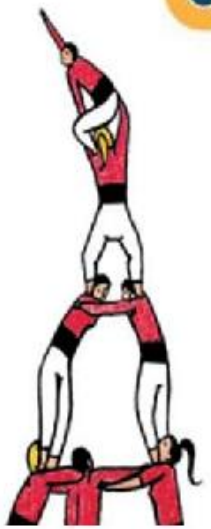




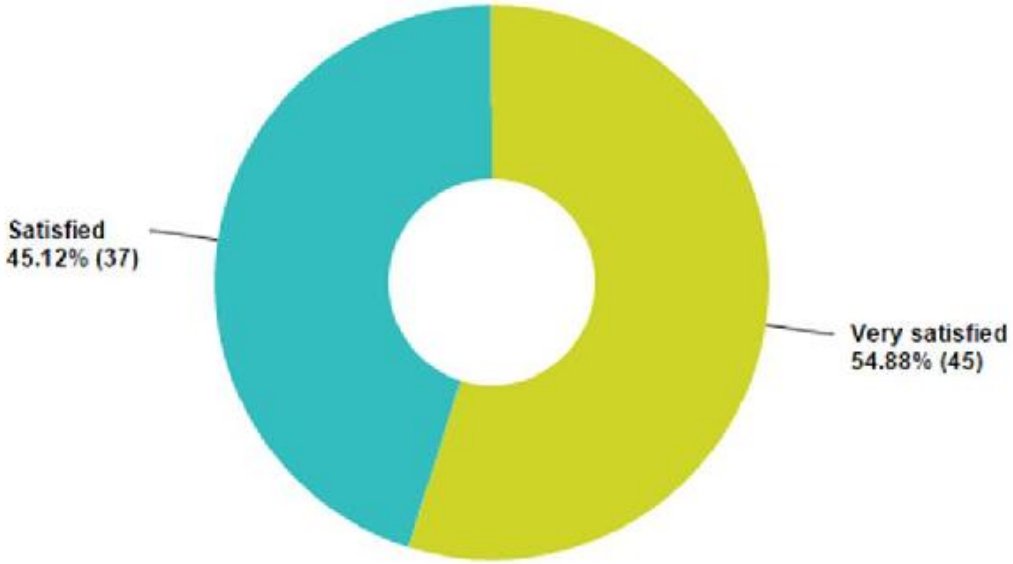
Based on 2014 data

Evaluations

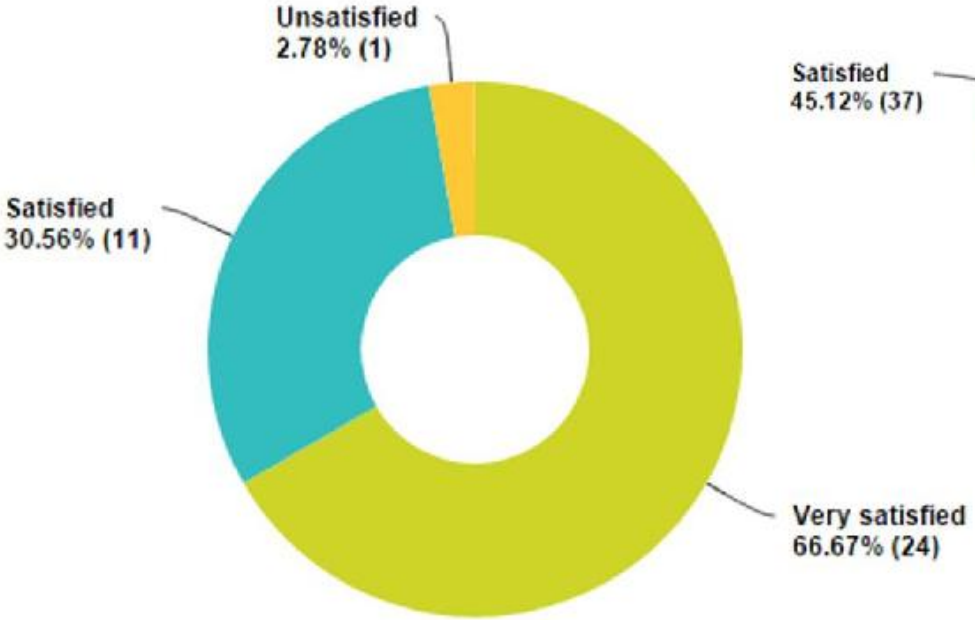
Overall, how satisfied are you with the onsite inspection process (preparation phase and onsite inspection)?

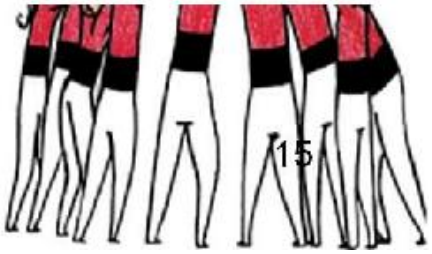


INSPECTORS



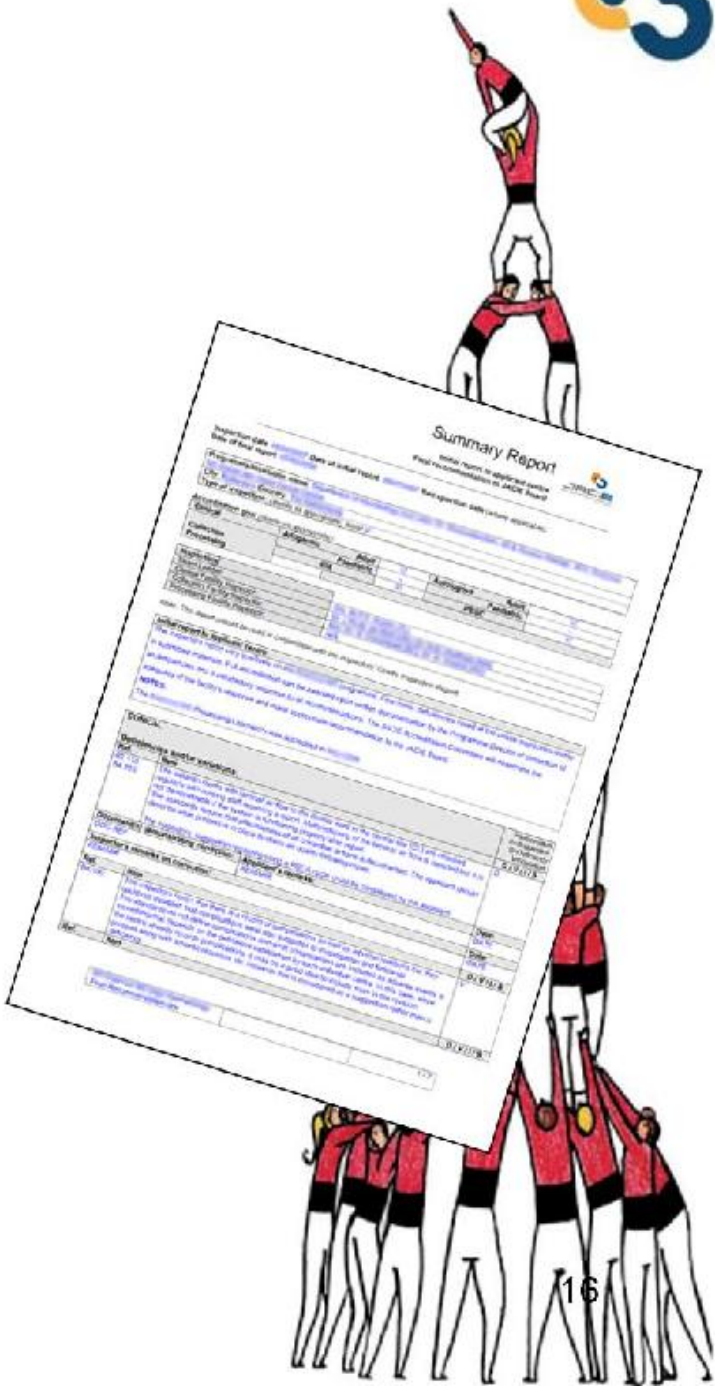
APPLICANTS





Report

- Fundamental part of the Accreditation Process!!!
- All decisions are made based on the report.
- Based on completed Inspection Checklist



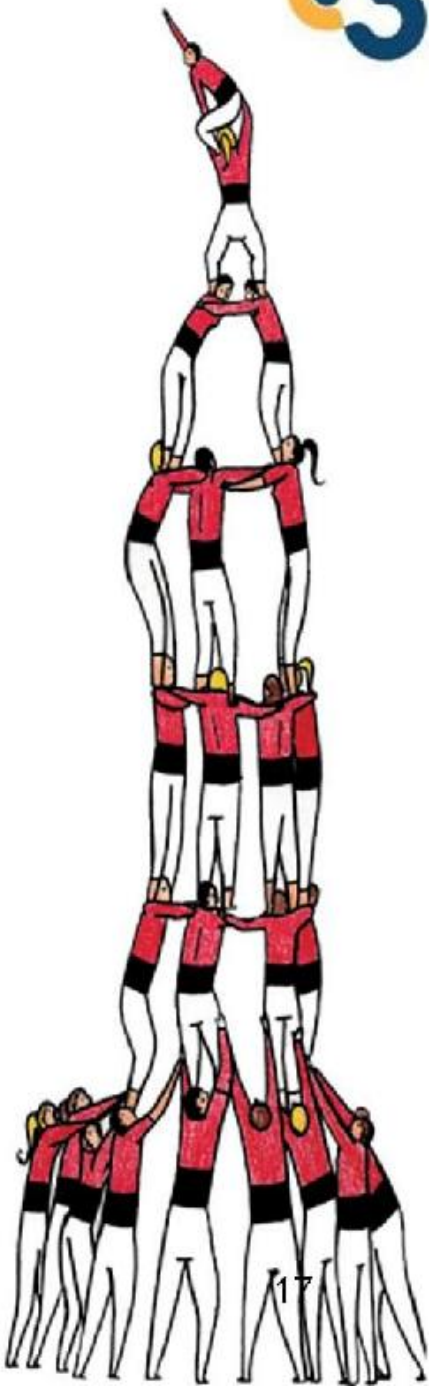
The report pathway

1.
Inspector sends report
to **JACIE Office**

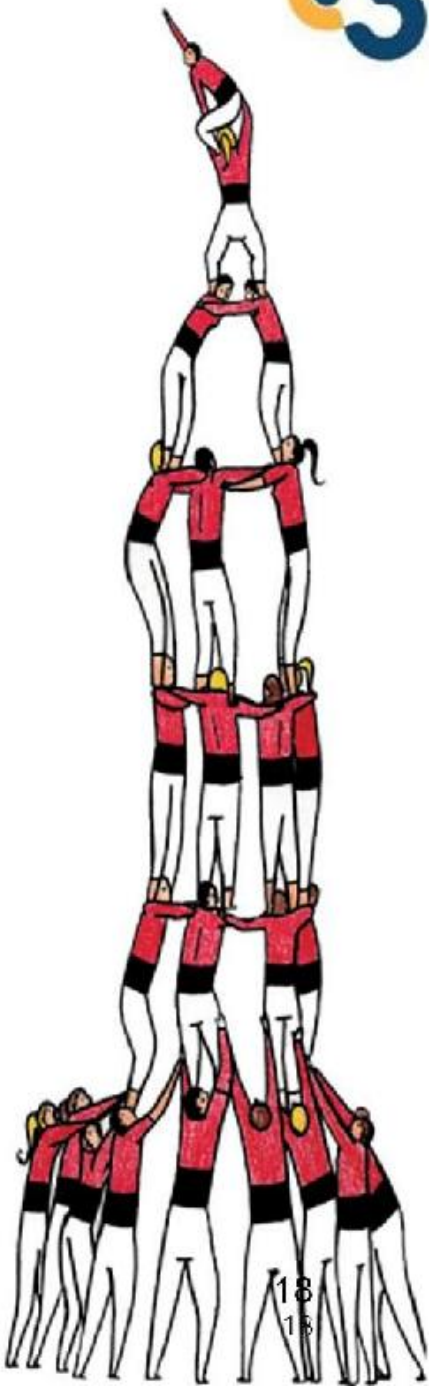
2.
Report reviewed by
Report Assessors

3.
Report Assessors Present report to
Accreditation Committee

4,
Report sent to Centre with recommendations



Accreditation Committee



Accreditation Committee

- Discusses each individual report and make recommendations

- Source of expert opinion

- Monthly teleconference

Accreditation Committee

Chair: Maria Vittoria Gazzola (Italy)

Clinical

John Snowden (UK)
Rafael Duarte (Spain)
Hellmut Ottinger (Germany)

Paediatric

Christiane Vermylen **(**Belgium)
Justyna Kanold (France)

Collection

Kim Orchard (UK)
Kristina Hölig (German)

Processing

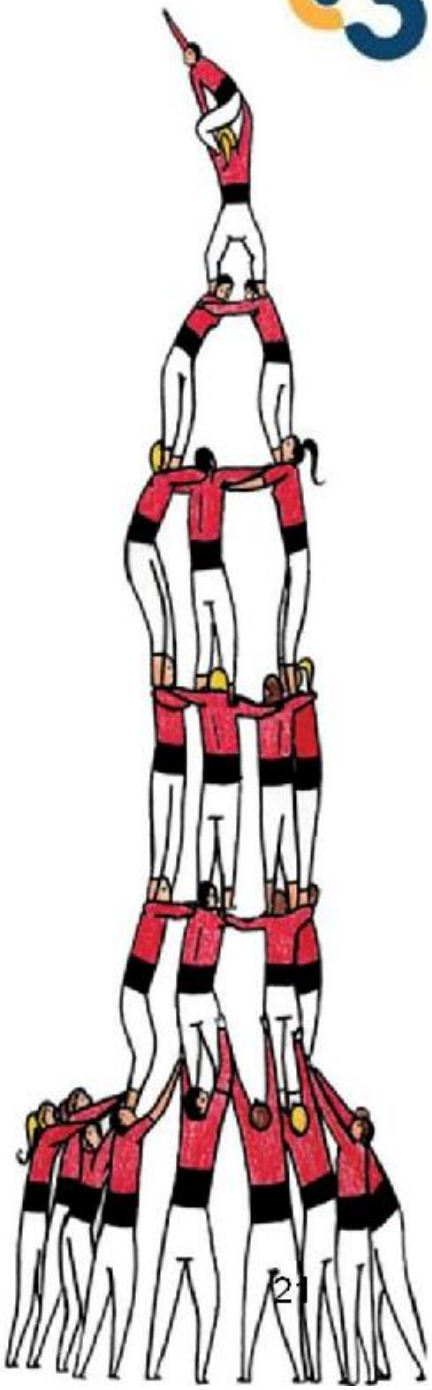
Dominic Latinne (Belgium)
Monique Grommé (The Netherlands)
Maria Vittoria Gazzola (Italy)

Corrections

"Well, nobody's perfect":

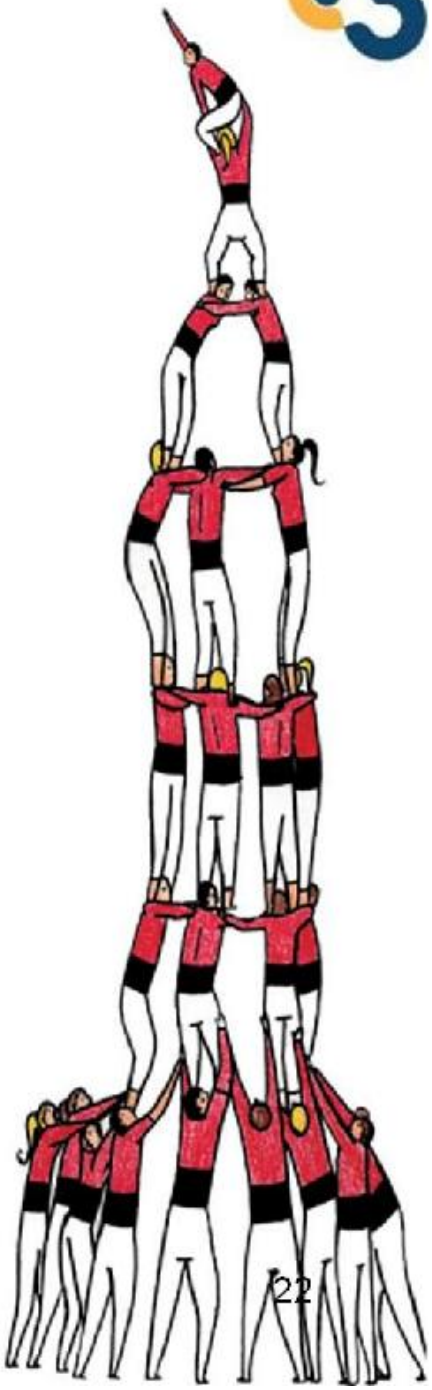
Osgood Fielding III

Some Like It Hot (1959)

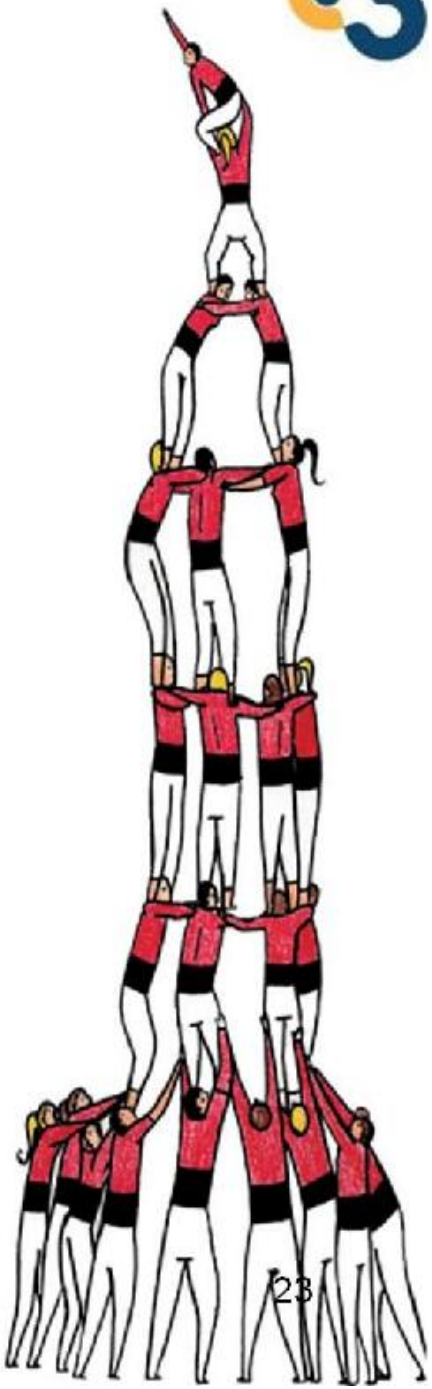


Corrections

- "99.99%" of inspections reveal deficiencies
- Great variety in seriousness of deficiencies
  - Vary from missing references in SOPs to dangerous storage areas
- Most cases, evidence of corrections is submitted electronically and reviewed by inspectors



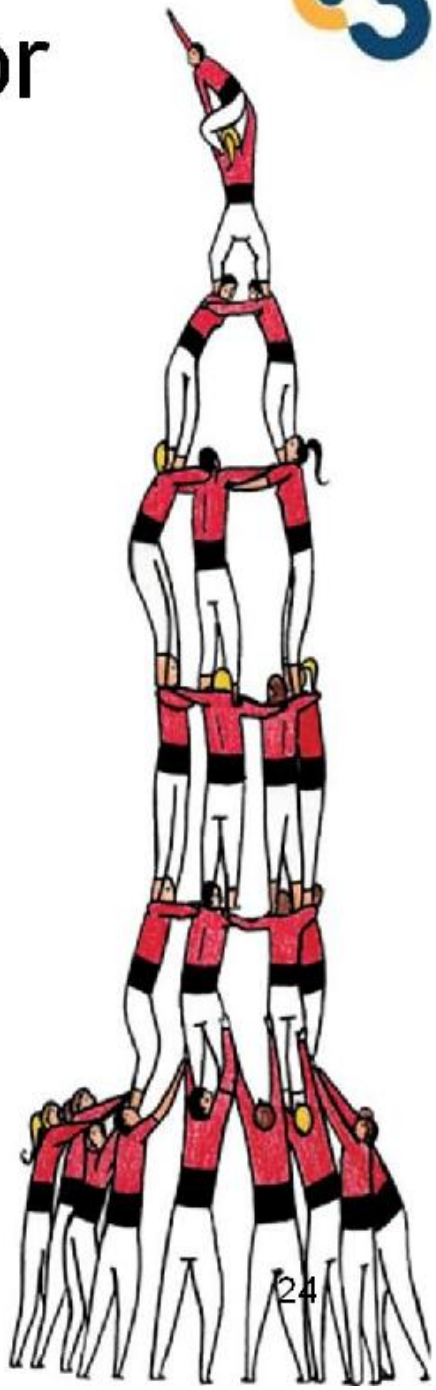
Review of corrections and/or need for revisit



Review of corrections and/or revisit

- The same inspectors assess evidence of corrections

- In certain cases, a revisit to the site may be required.
  - extensive failures in the quality management system,
  - new contruction since inspection



Accreditation

- Accreditation awarded when inspectors are satisfied that all points have been resolved

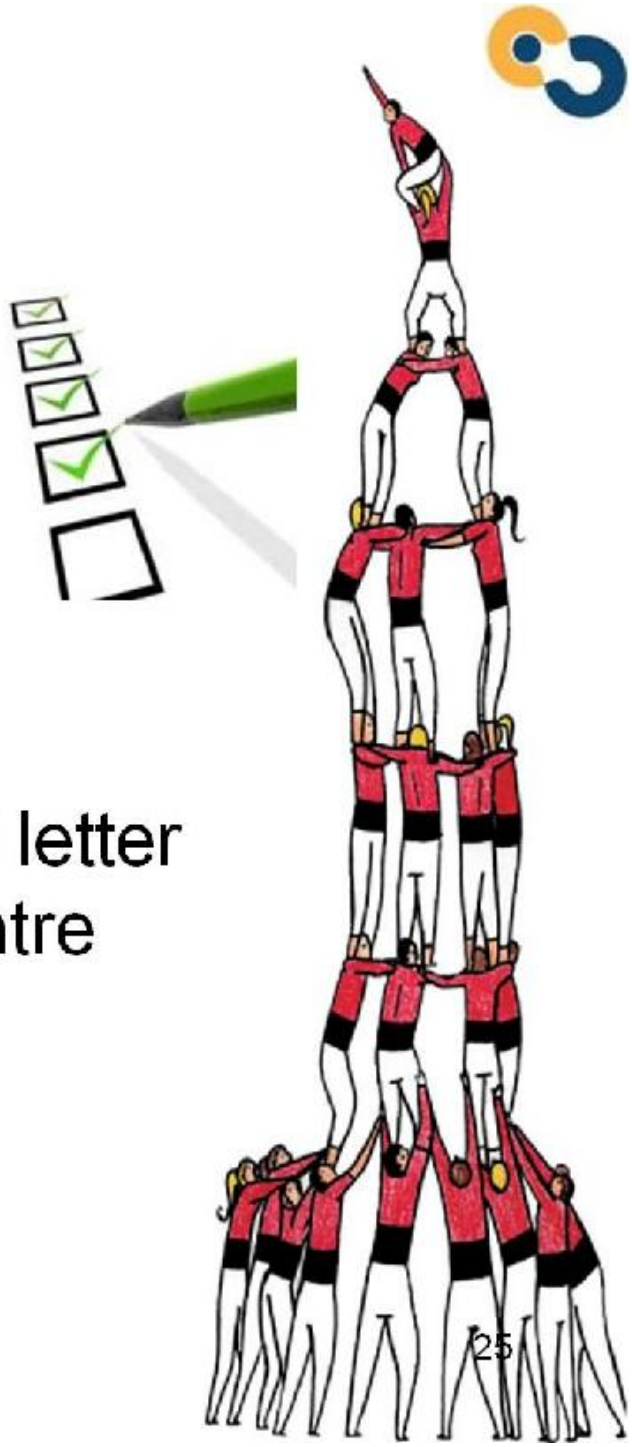
Joint Accreditation Committee ISCT-EBMT
certifies that

Centre de Lutte contre le Cancer
de Haute-Normandie (CLCC),
Centre Henri Becquerel
Rouen, France

Autologous & Allogeneic Transplantation in Adult Patients
Collection of HPC, Marrow
Collection of HPC, Apheresis
Cell Processing

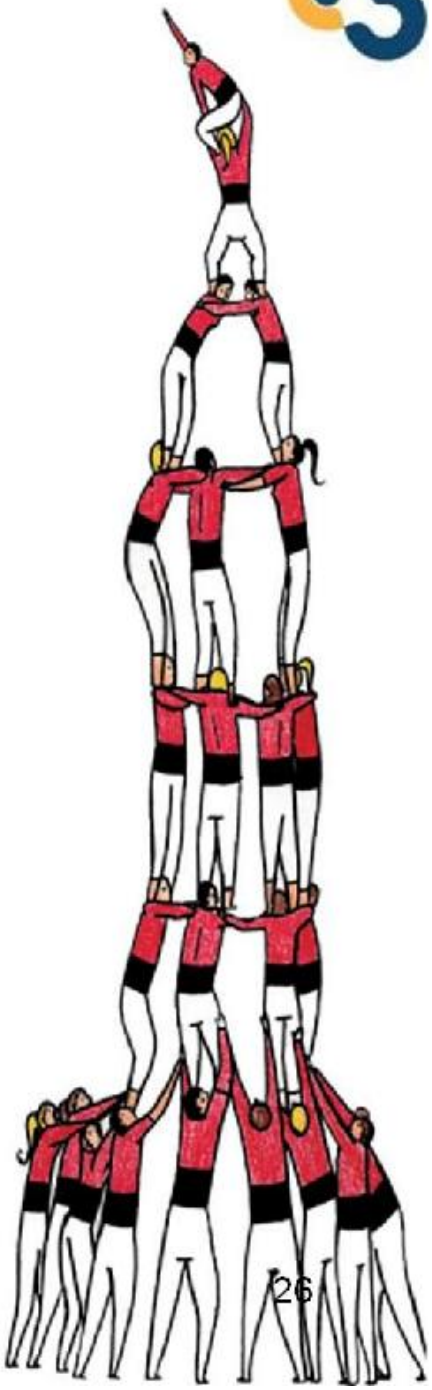
Programme Director: Prof. Hervé Tilly

- Certificate and letter issued to the centre



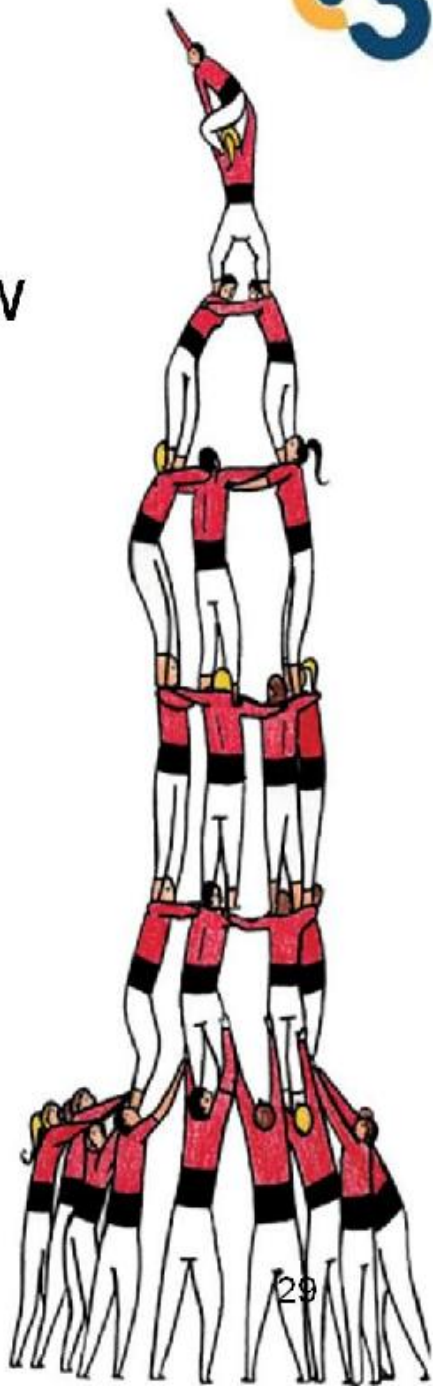
Accreditation

- Accreditation for 4 years from date of award
  - If a centre takes more than 9 months to resolve deficiencies, JACIE may award accreditation from date of inspection
- Annual report – short summary of activity and changes
- Interim review at end of year 2 of accreditation



Interim audit

- At end of year 2 of accreditation
- Documentation review will focus on how the quality management system is functioning
  - Evidence of audits
  - QM meetings
  - SOP review
  - Etc.
- Based on standards i.e. no new requirements
- May result in on-site visit



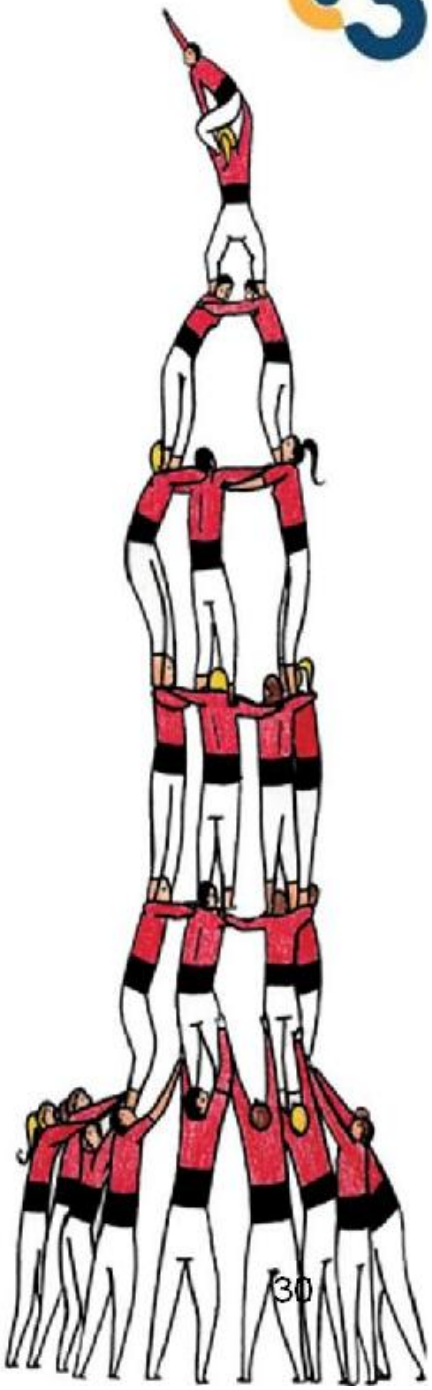
Fees (from 1 Jan 2015)

- **Registration Fee (non-refundable)**:
  €3,500 on application (*applicable to all applications, both first-time and reaccreditation, and non-refundable*)

- **Inspection Fees:**
- €2,100 charged per area to be inspected.

- **Supplementary Fee**
  €1,000 per each additional site

- Applications from centres whose staff members have participated in an inspection event(s) in the 4 years preceding submission of the new application will qualify for a discount of 10% per event up to a maximum of 20%.



Pre-audit documentation: 11.5 hr

Teleconference: 0.5 - 1 hr

Inspection: 1.5 days

\+ Inspection Report

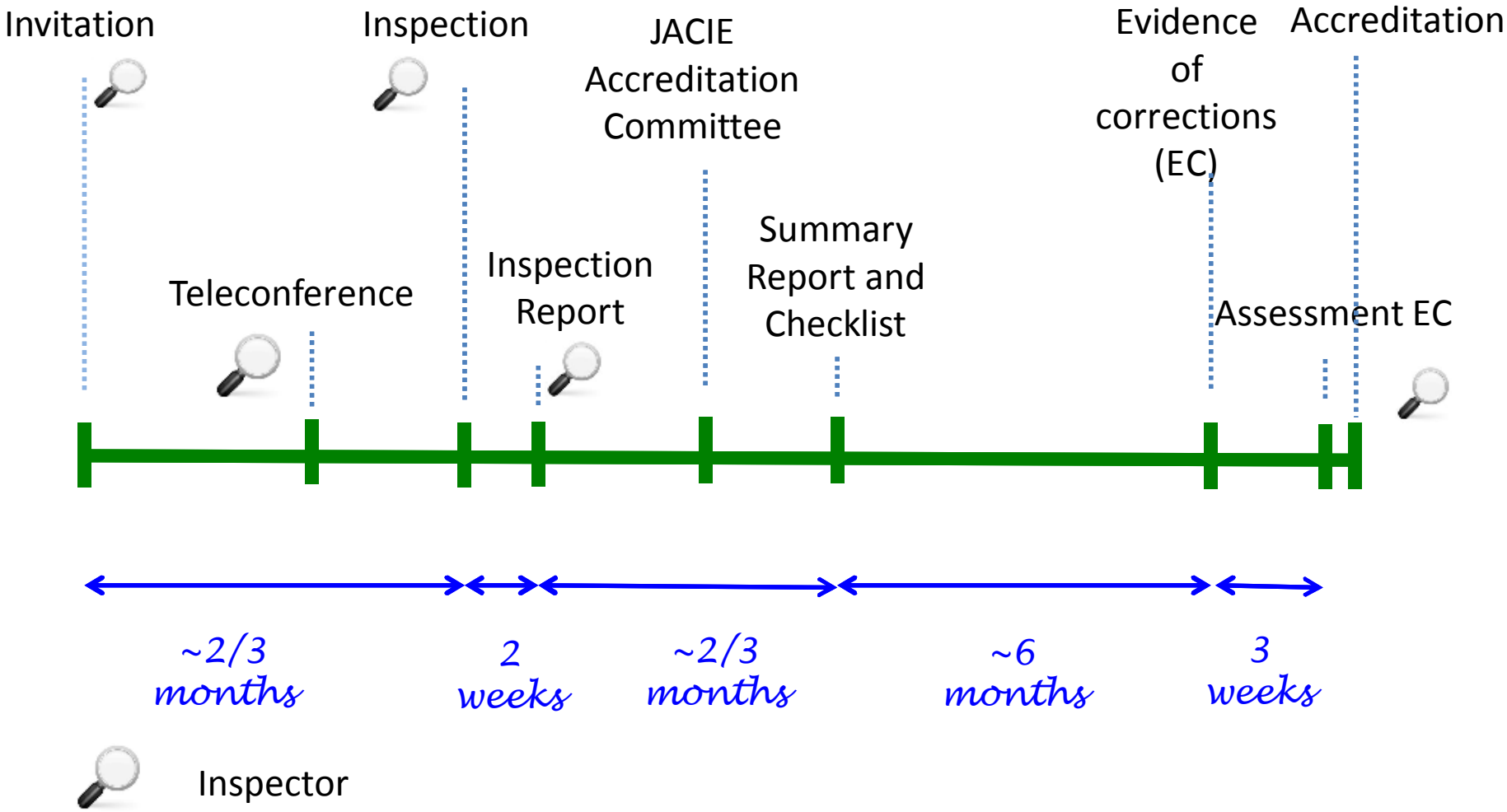
Evidence of corrections

Interim Audit

JACIE Inspector

TIMELINE

YOU
ARE
HERE
NOW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Checklist
Assessment EC
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months
2
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months
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months
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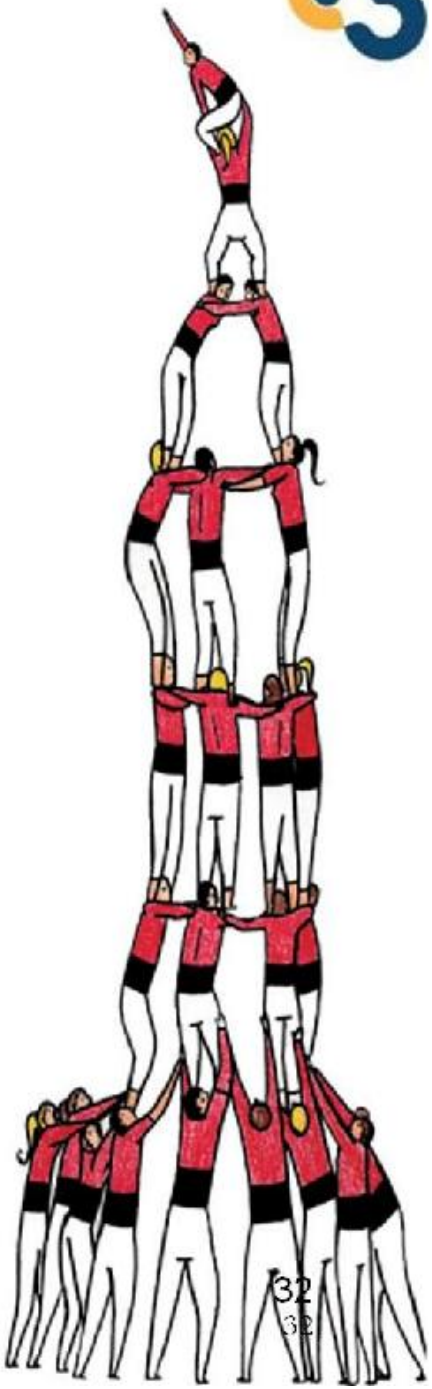
weeks
Inspector

- Thank you for listening
- Any questions?