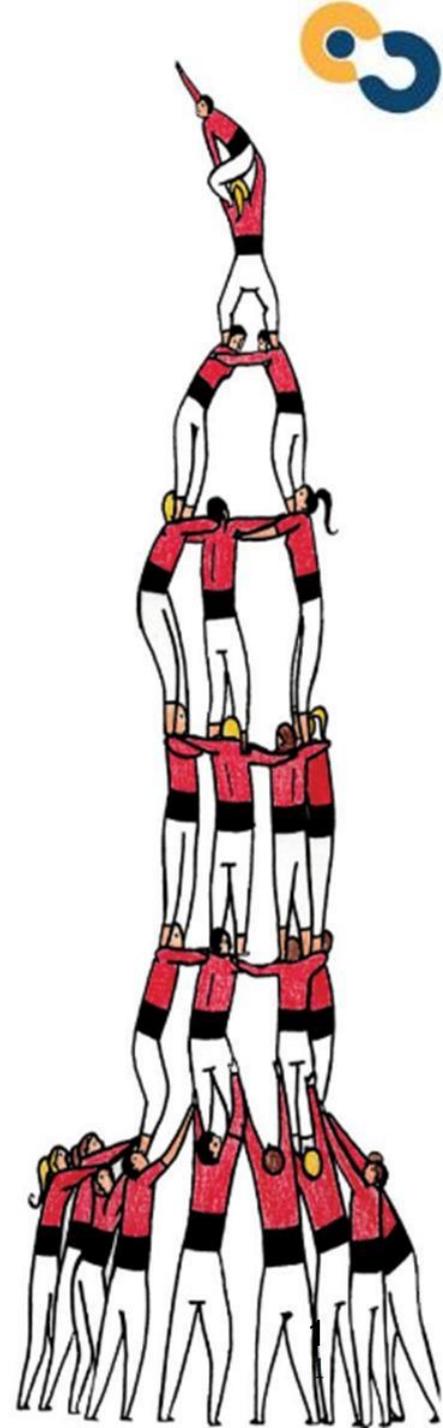


The JACIE Accreditation Process

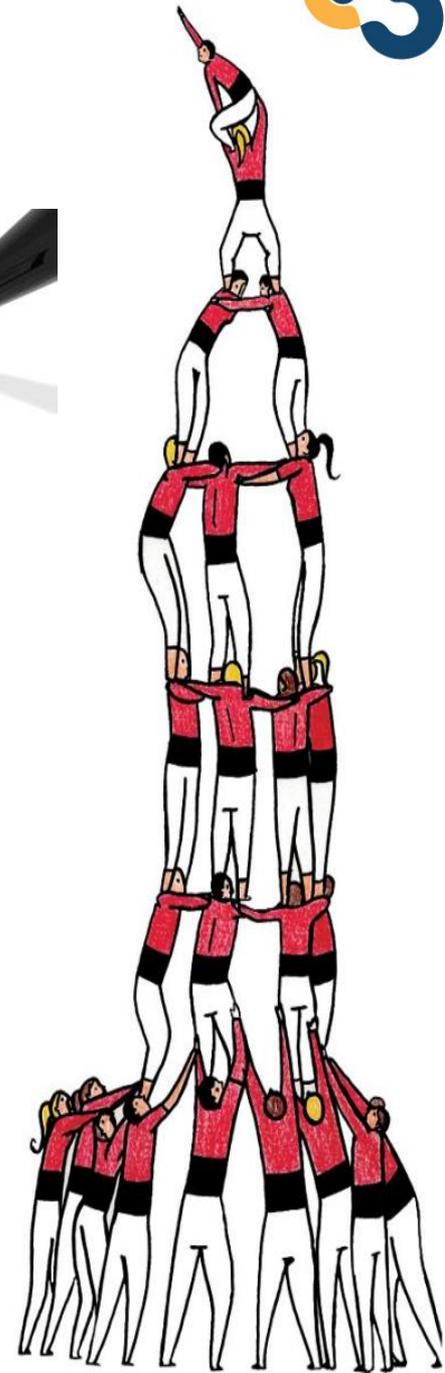
JACIE Office,
Barcelona, Spain



Contents



- Inspection
- JACIE Accreditation Committee
- Post-inspection
- Accreditation
- Interim Audit



Accreditation Process




Invitation


Inspection


JACIE
Accreditation
Committee


Evidence
of
corrections
(EC)


Accreditation


Pre-Inspection
Documentation


Teleconference


Inspection
Report


Summary
Report and
Checklist


Assessment EC

PRE-INSPECTION

INSPECTION

POST-INSPECTION


Inspector

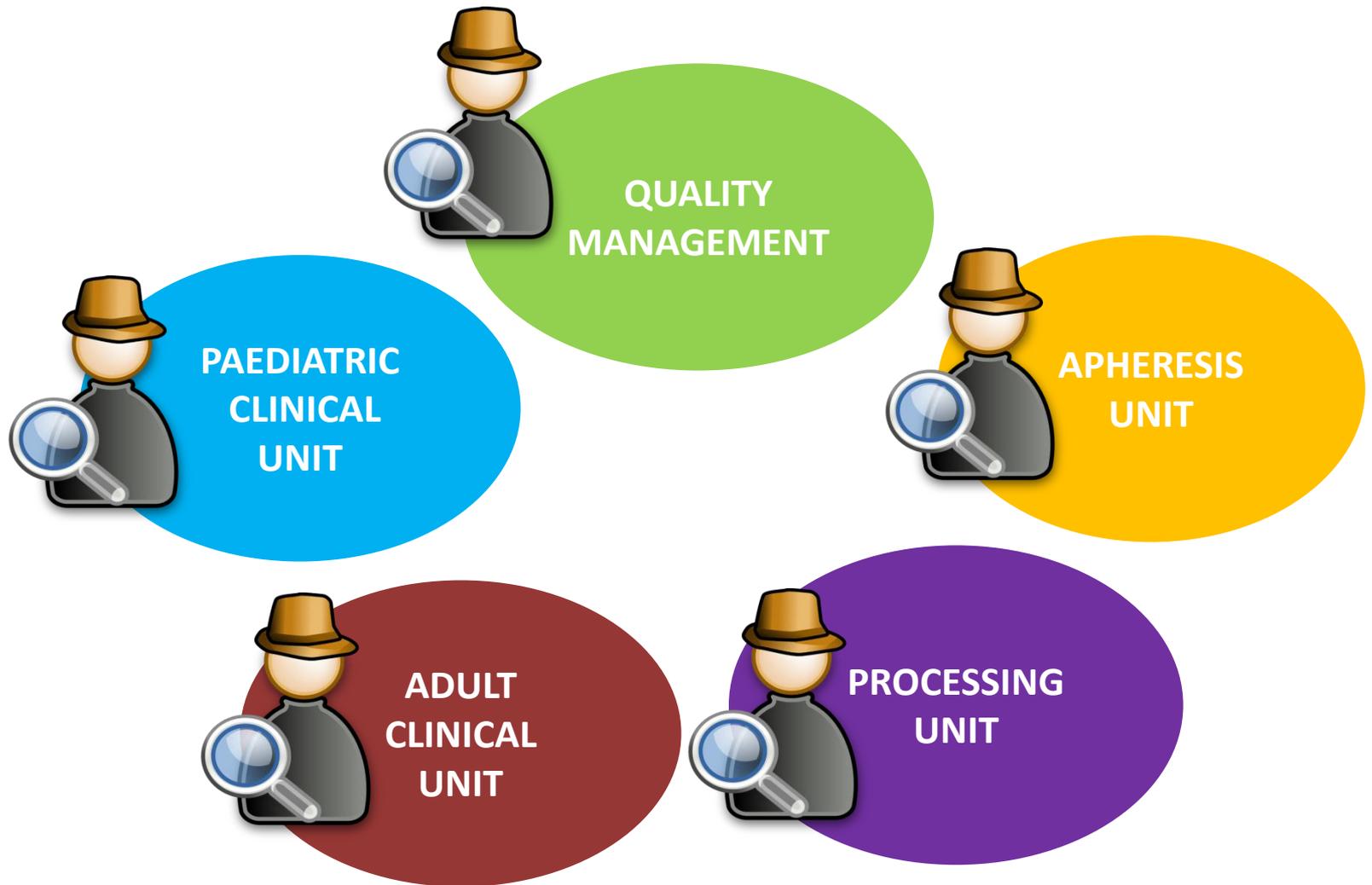

Center


JACIE Office

Inspection



Current Inspection Team



Quality Management Inspectors



CURRENT INSPECTOR POOL (October 2017) = 70

ESTIMATED INSPECTOR POOL (January 2018) = > 80

QMI :

Belgium, Czech Republic, Denmark, Germany, Greece, Ireland, Italy, Macedonia, Netherlands, Nigeria, Saudi Arabia, Spain, Sweden, Switzerland, Turkey, UK

Distribution of Standards to be Inspected

1st Option : QM Inspector available



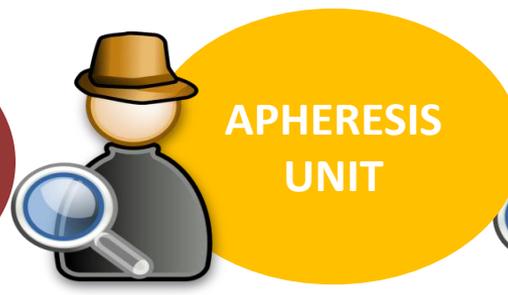
Part B/CM/C/D 4 QM excluding:

- Outcome analysis
- Tracking & traceability/labeling requirements
- Qualification
- Validation

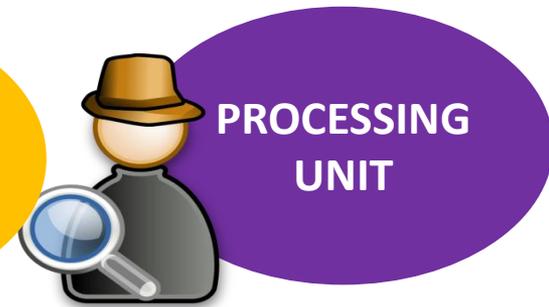
Parts B/CM/C/D 5 Polices & Procedures



Part B + Part CM (- QM)



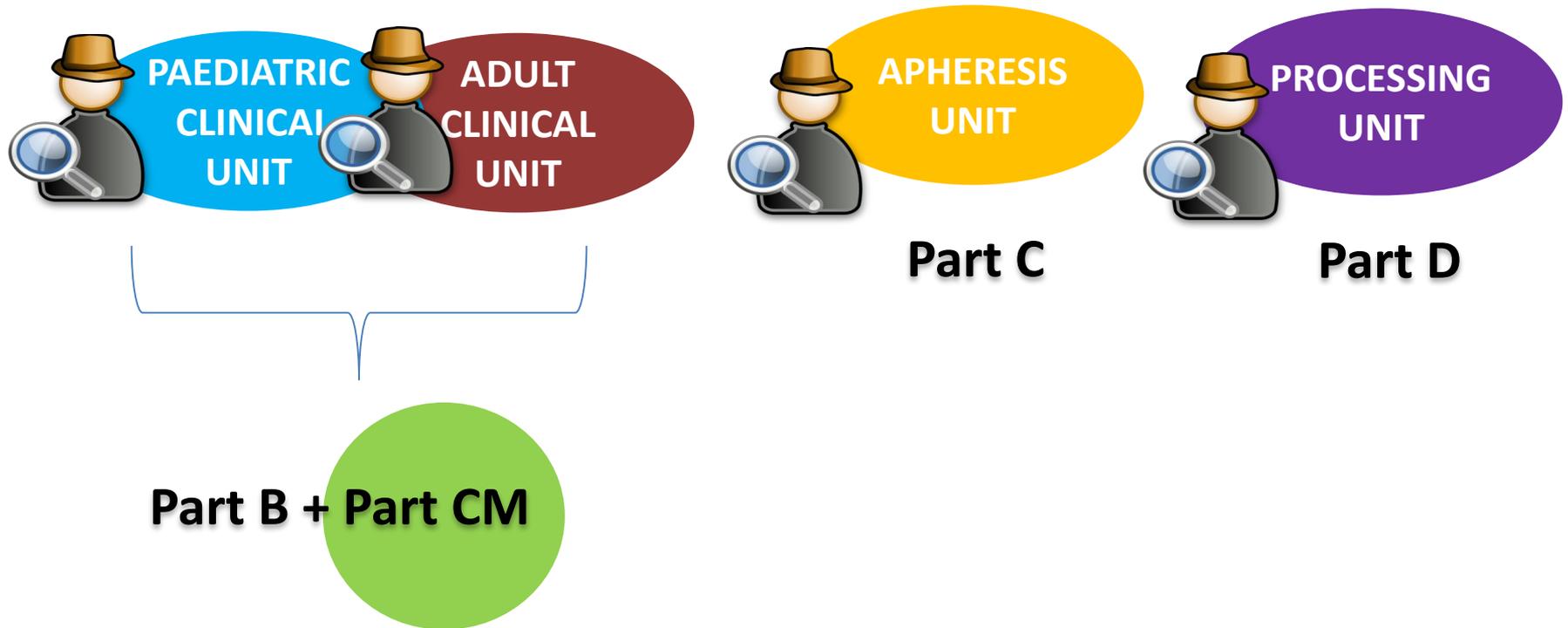
Part C (- QM)



Part D (- QM)

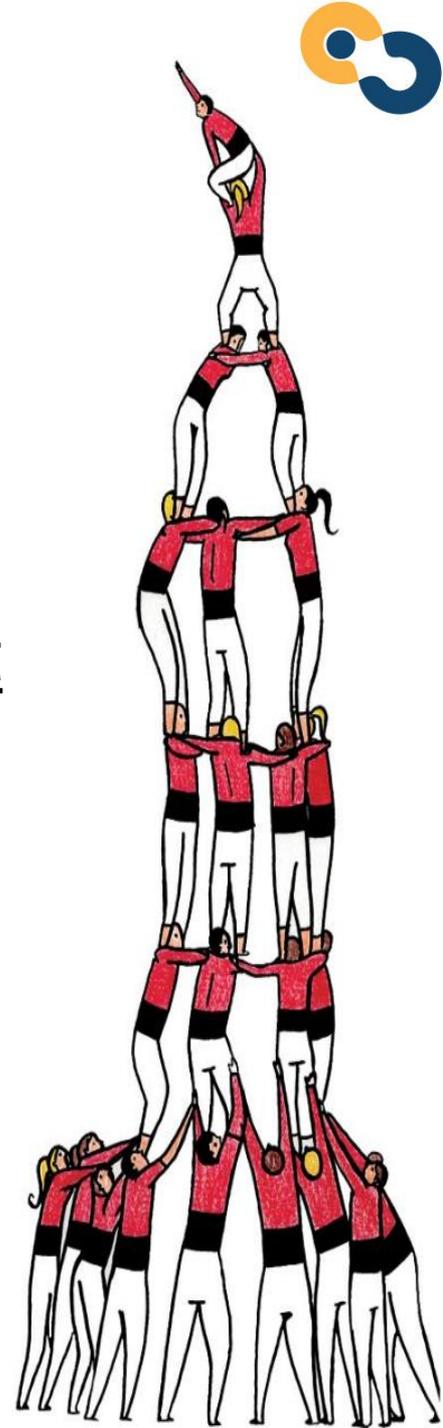
Distribution of Standards to be Inspected

2nd Option : No QM Inspector available



Inspection Timetable

- Proposal made by the Team Leader
- Reviewed by the center who can insist on reasonable changes if necessary
- Usually 1.5 days



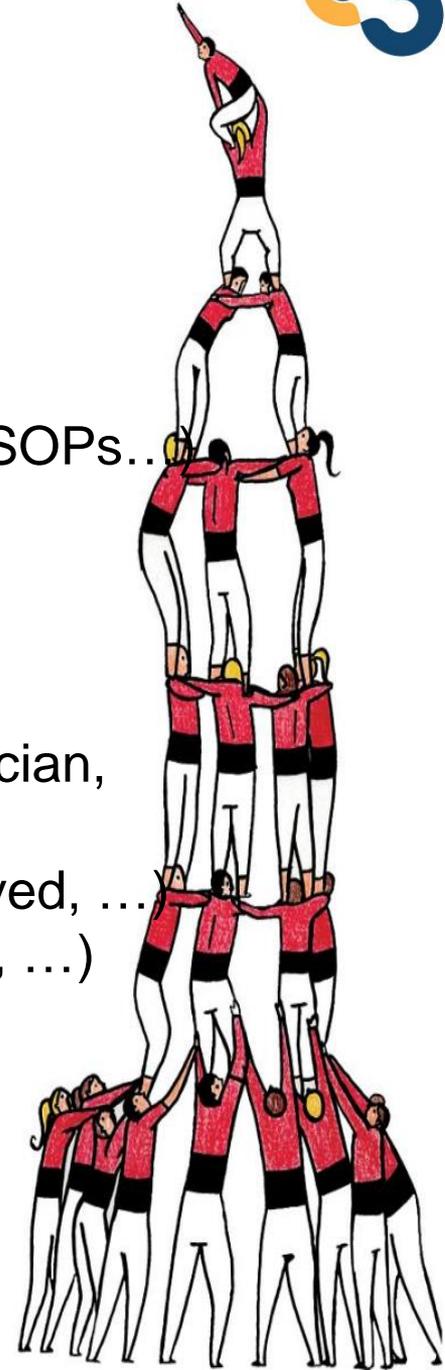
Sample Timetable



- 1st Half Day – Day 1
 - Arrival to site
 - Presentation Inspector Team
 - Presentation Programme
 - Review documentation (MEDA/B, Quality Manual, SOPs...)

- 2nd Half Day – Day 1
 - Tour of facilities
 - Interviews
 - Clinical (Programme Director, Transplant Physician, Nurse, Quality Manager, ...)
 - Cell Collection (Facility Director, any staff involved, ...)
 - Laboratory (Lab Director, Lab Processing Lead, ...)

- 3rd Half Day – Day 2
 - Continue tour and interviews
 - Exit Meeting with Programme Director
 - Closing Meeting

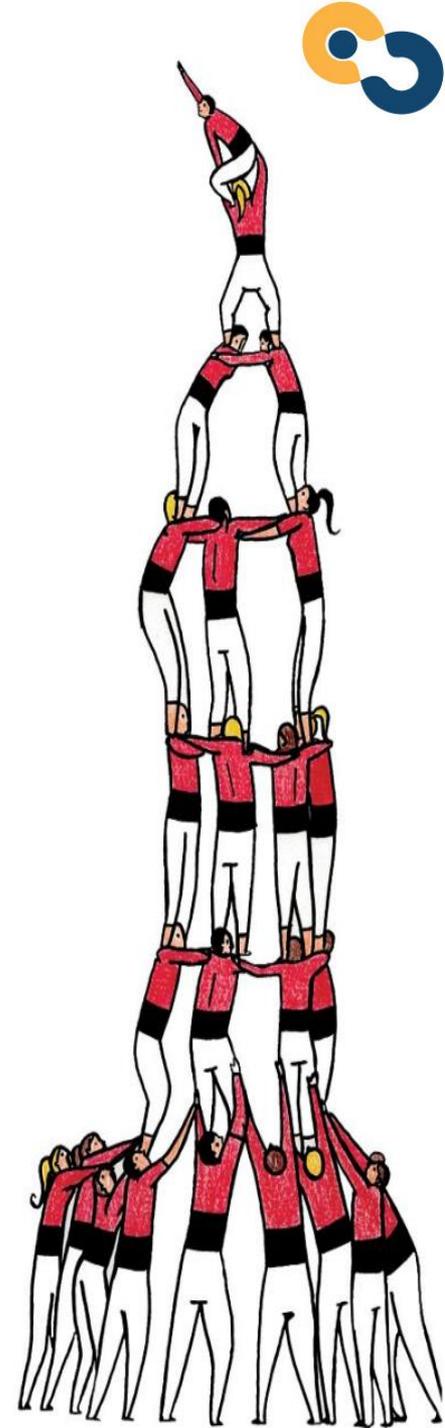


Inspection

○ Opening Meeting:

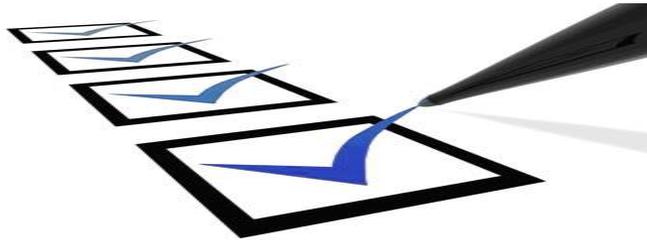
- Introduction Inspectors
- Confidentiality
- Explain
 - Purpose of the Inspection
 - The roles of the different Inspectors
 - Responsibilities of the Inspectors
- Point of reference (standards)
- Scope of the Inspection
- Working method during the Inspection
- Confirm the program
 - Lunch and coffee breaks
 - Inspection Plan
 - Closing meeting

Create a good cooperative atmosphere



Inspection

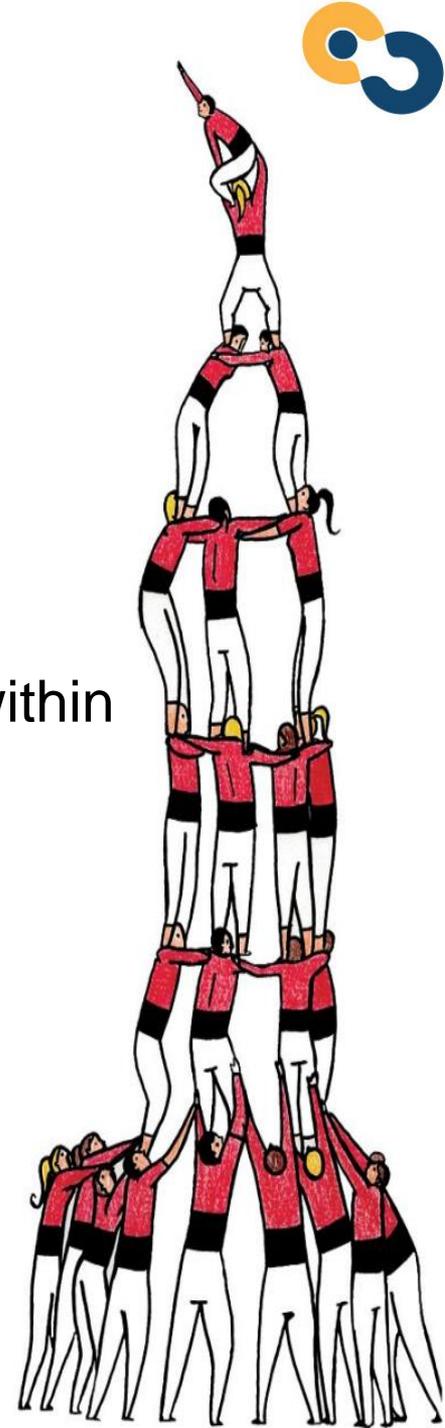
- During the Inspection:
 - Thorough examination of all aspects of the programme.
 - Verification of the applicant's completed checklist



Inspection

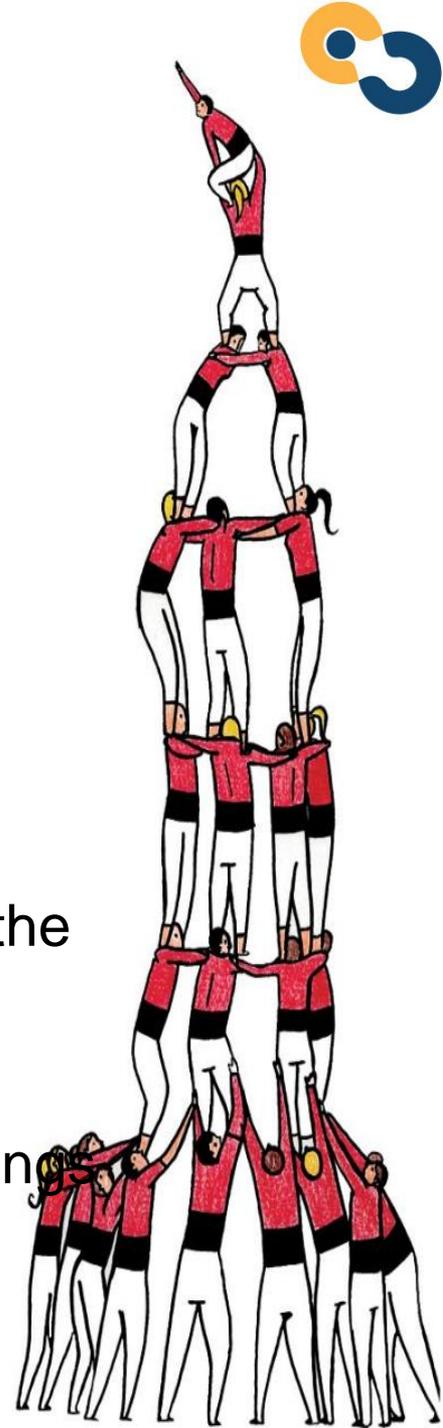
○ At the end of the Inspection:

- Inspection Team Meeting
 - discuss findings within team
 - evaluation and review of findings
 - grade findings and maintain gradation within team
- Exit Meeting Programme Director
 - Private
- Closing Meeting
 - do not comment on the possible outcome



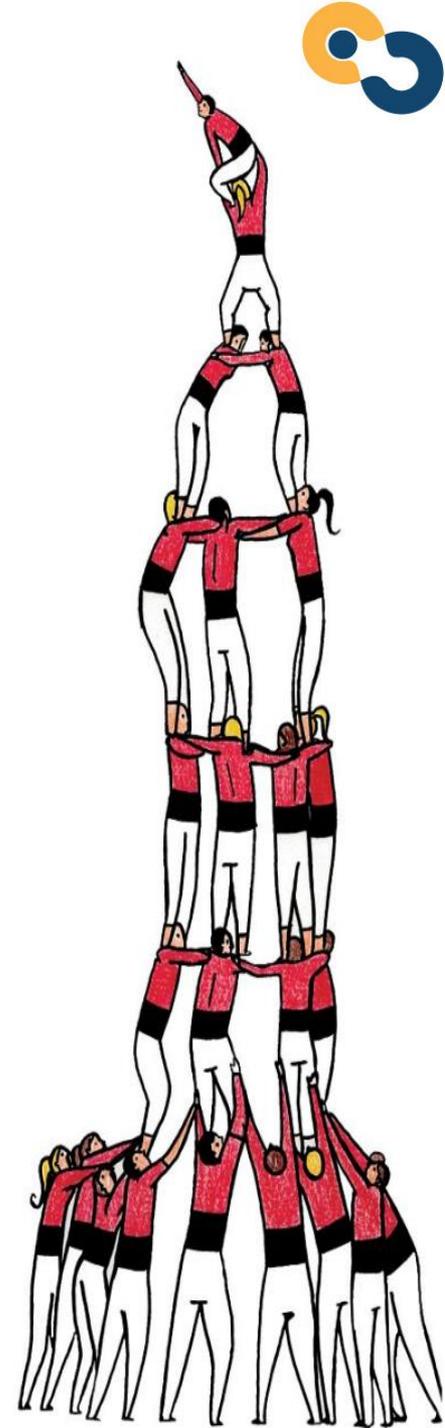
Inspection

- Closing Meetings:
 - You are in charge of the meeting
 - Thank the ward/department
 - Repeat confidentiality.
 - Repeat in general the scope of the inspection.
 - Report things that are not in order
 - Inspection = “random” check and therefore not complete.
 - Suggest questions and discussions for end of the meeting.
 - Refer to later report
 - Each team-member can explain their own findings
 - Invite people to ask questions - avoid conflicts



Evaluation

- Applicants / Inspectors
 - Complete survey online
 - Link in the email from Aurea
 - Opportunity to give praise or raise concerns
- **Applicants Feedback + Inspectors Feedback = Improvement of the accreditation process**



Evaluation



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**

.....



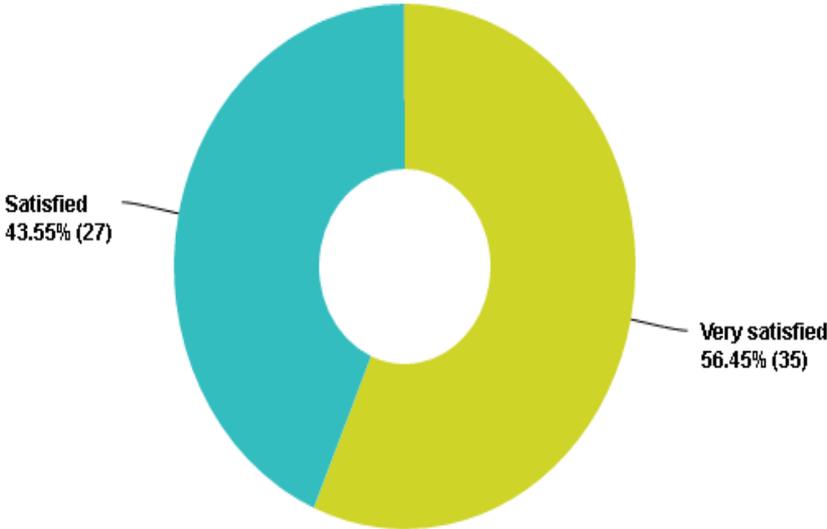
JACIE Survey - 2016



INSPECTOR'S SATISFACTION

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

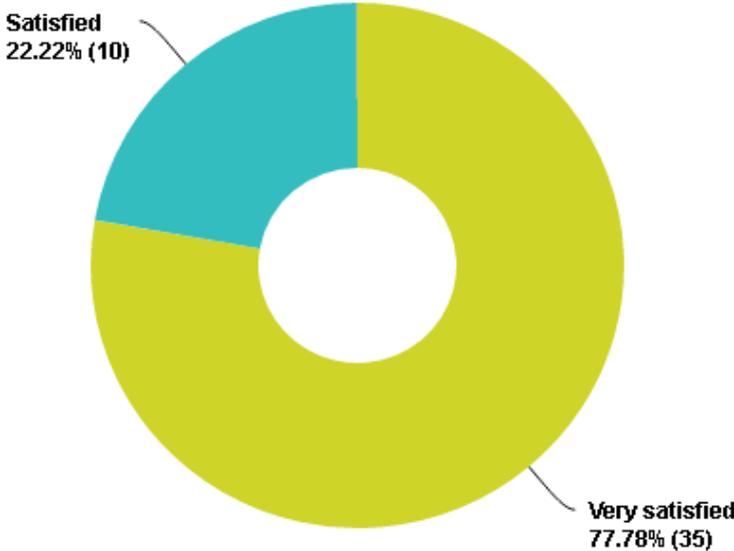
Answered: 62 Skipped: 4



CENTER'S SATISFACTION

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

Answered: 45 Skipped: 1



The Inspection Report

- Return to the Team Leader and the JACIE office
 - Checklist and Word document
- Fundamental part of the Accreditation Process
 - All decisions are made based on the report

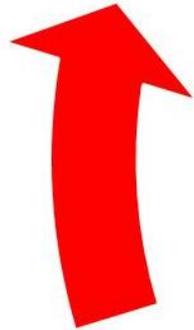


The Inspection Report



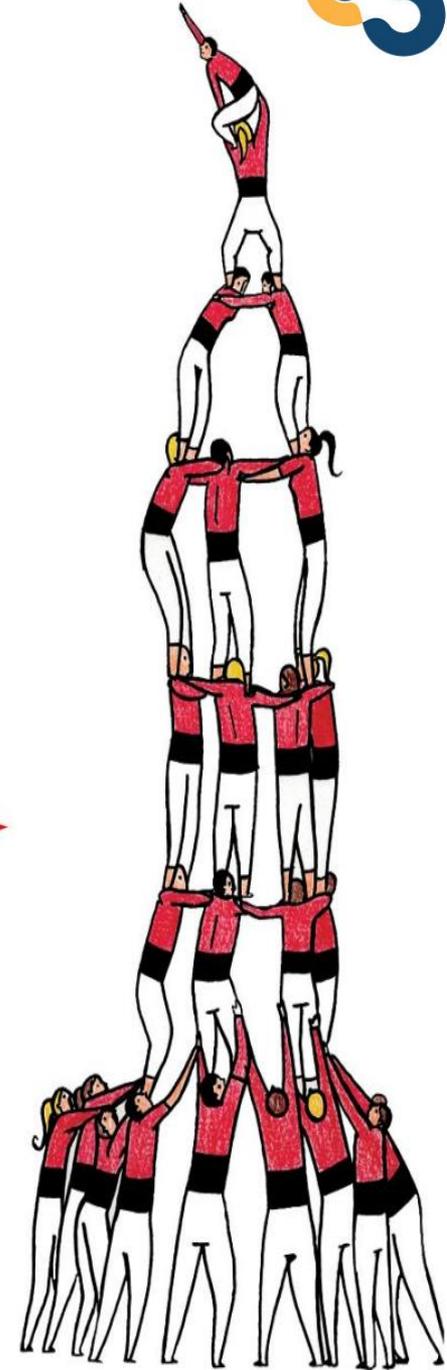
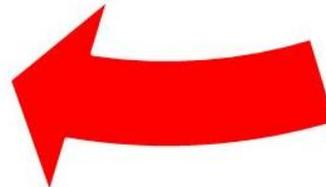
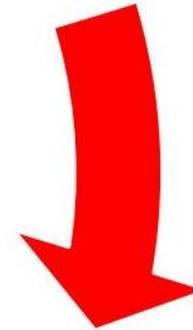
4,
Report sent to
Centre with
recommendations

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

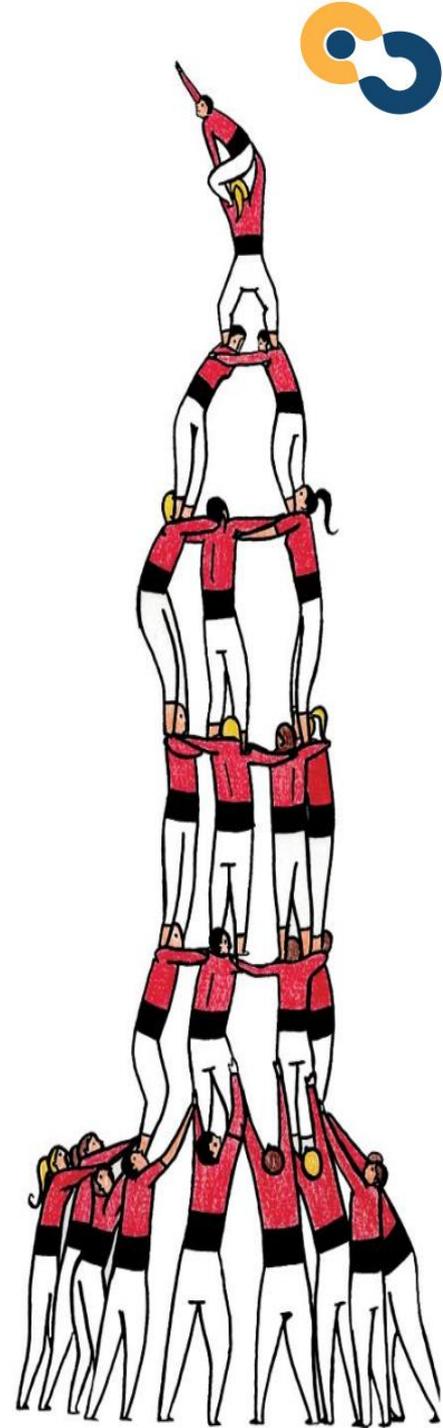


3.
Report Assessors
Present report to
**Accreditation
Committee**

2.
Report reviewed
by
**Report
Assessors**



JACIE Accreditation Committee - JAC



The Accreditation Committee

- Discusses each individual report and make recommendations
- Source of experts' opinion
- Monthly teleconference



The Accreditation Committee



Chair: Kim Orchard (UK)

Clinical

Riccardo Saccardi (Italy)

Kim Orchard (UK)

Hellmut Ottinger (Germany)

Lucien Noens (Belgium)

Andreas Humpe (Germany)

Almudena de la Iglesia
(Spain)

Paediatric

Christiane Vermylen (Belgium)

Justyna Kanold (France)

Quality Management

Renza Monteleone (Italy)

Tuula Rintala (UK)

Andreas Humpe (Germany)

Lynn Manson (UK)

Collection

Kim Orchard (UK)

Kristina Hölig (Germany)

Justyna Kanold (France)

Lucien Noens (Belgium)

Tuula Rintala (UK)

Lynn Manson (UK)

Andreas Humpe (Germany)

Valerie Lapierre-France
(France)

Olga López (Spain)

Processing

Dominique Latinne (Belgium)

Monique Grommé
(Netherlands)

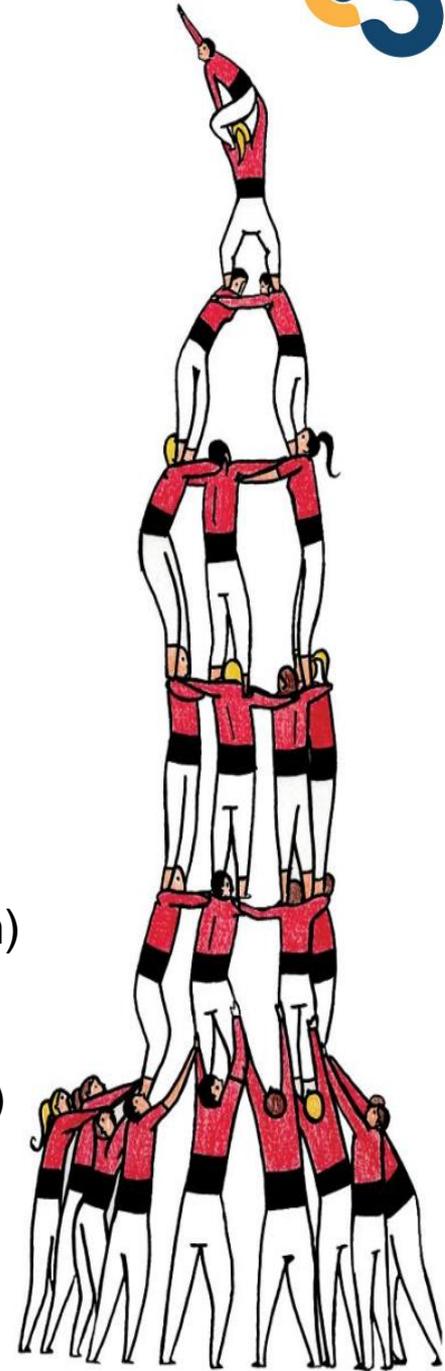
Maria Vittoria Gazzola (Italy)

Valerie Lapierre (France)

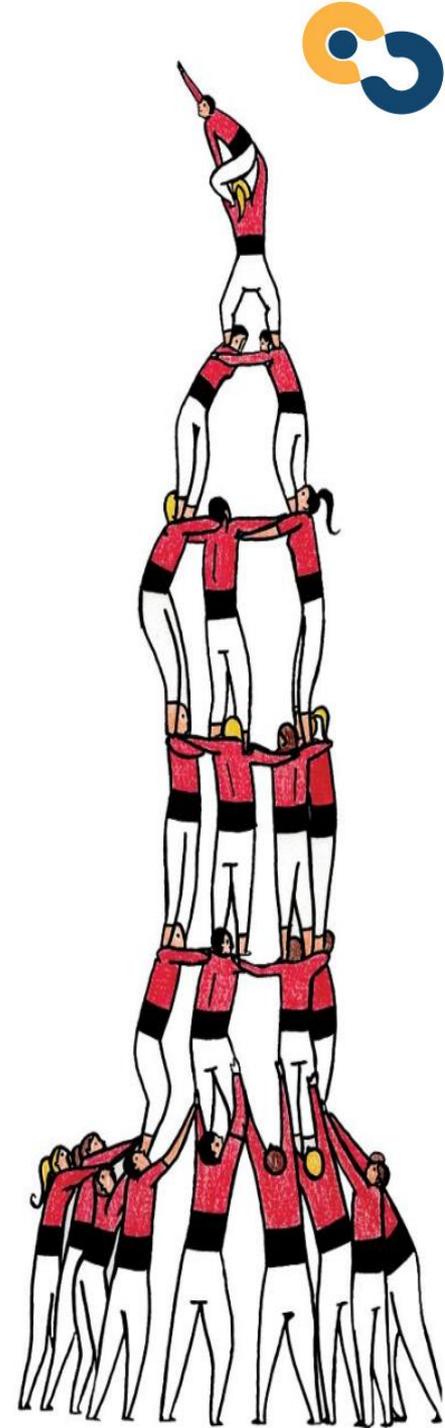
Ender Altıok (Turkey)

Dania Arabi (Saudi Arabia)

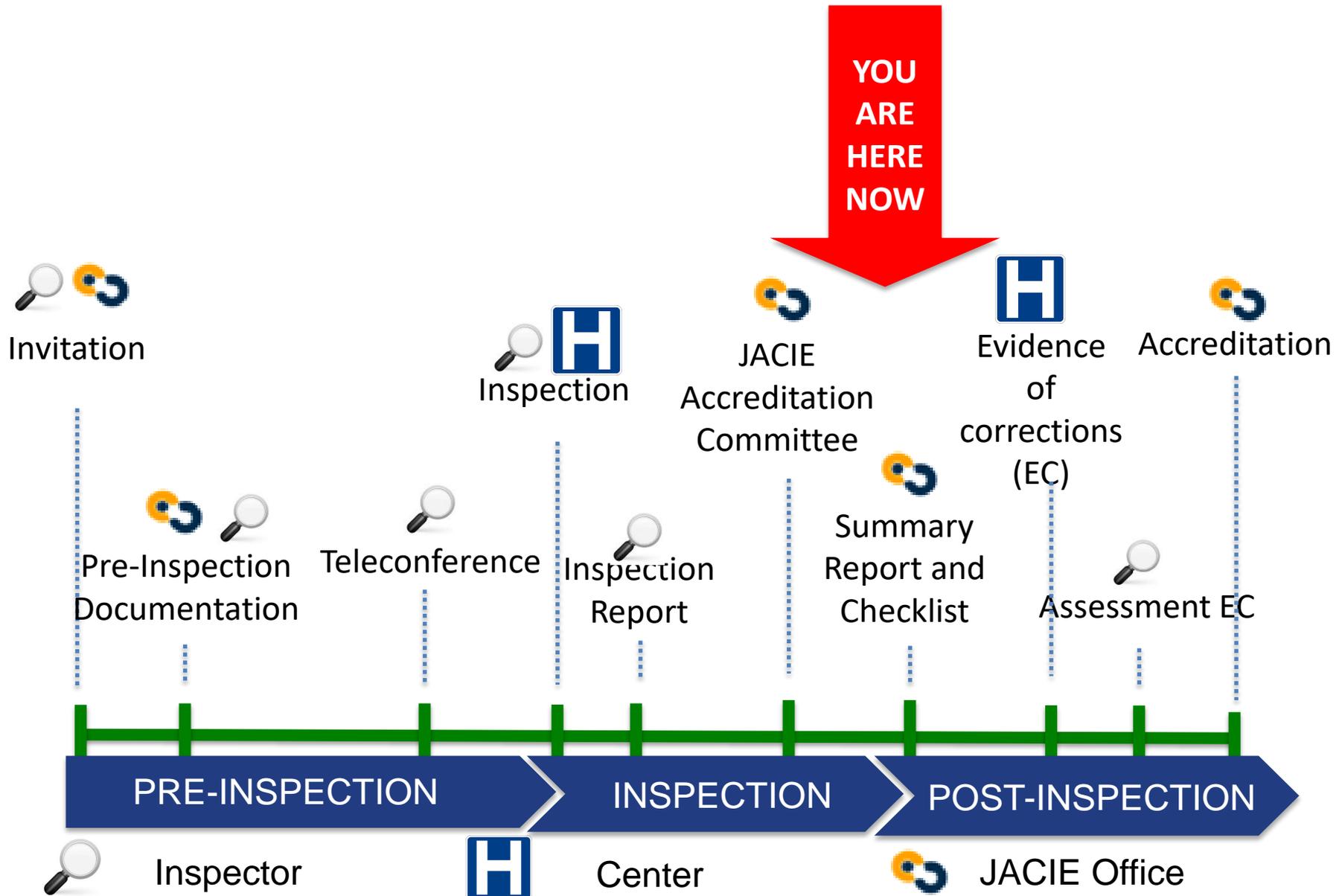
Olga López (Spain)



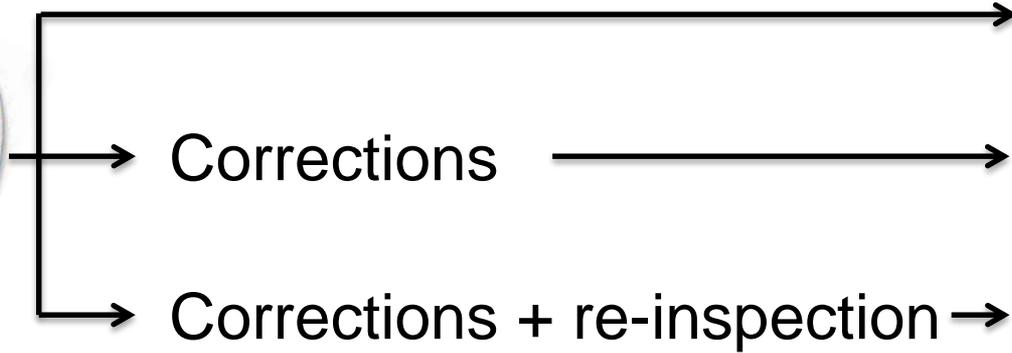
Post-Inspection



Accreditation Process

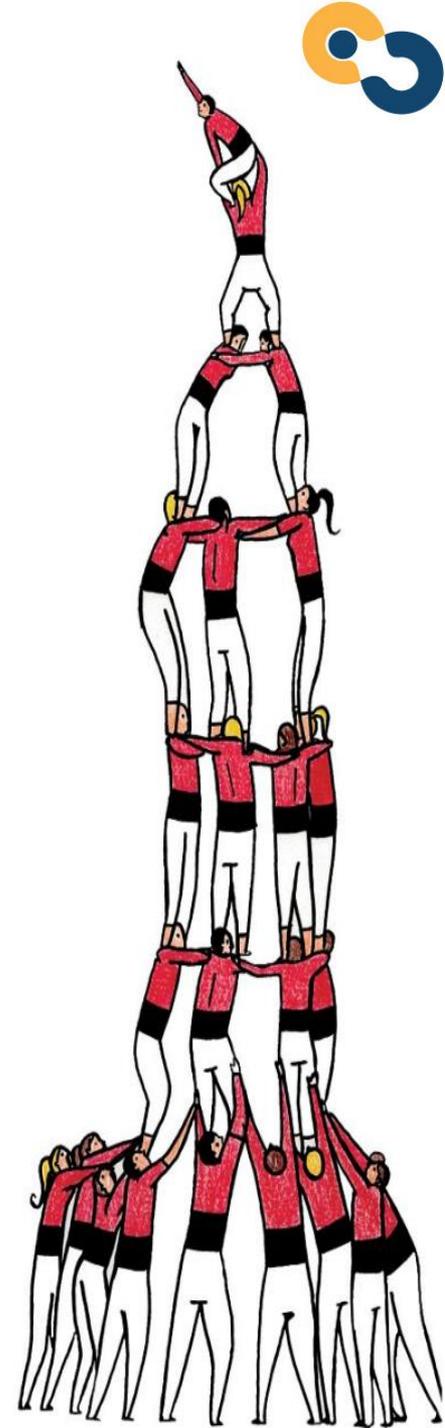


Possible Outcomes



Corrections

- 99,99% of inspections reveal deficiencies
- Great variety in seriousness of deficiencies
(ex: missing reference SOP, dangerous storage áreas, ...)
- Most cases, evidence of corrections is submitted electronically and reviewed by inspectors



Corrections

- Applicants provide evidence of corrections
 - Checklist
 - Supporting documentation



Inspector Review

- Same Inspectors review/assess the evidence of corrections
- A re-visit may be required:
 - Extensive failures in the quality management system
 - New construction since inspection



Accreditation



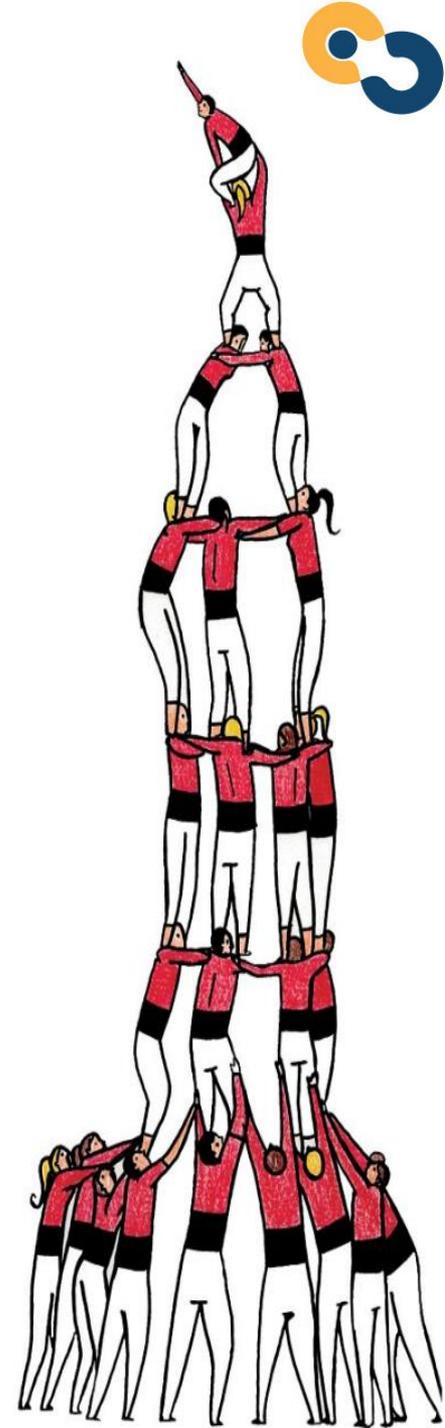
Accreditation

- Awarded
 - Inspectors confirm all points are resolved
 - JAC don't have further comments
- Certificate and letter

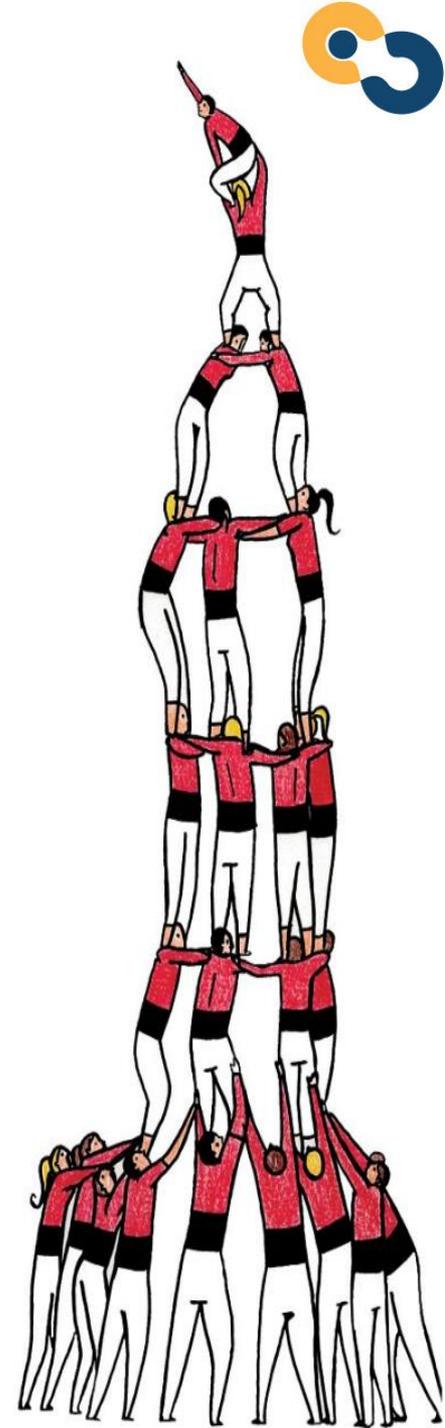


Accreditation

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

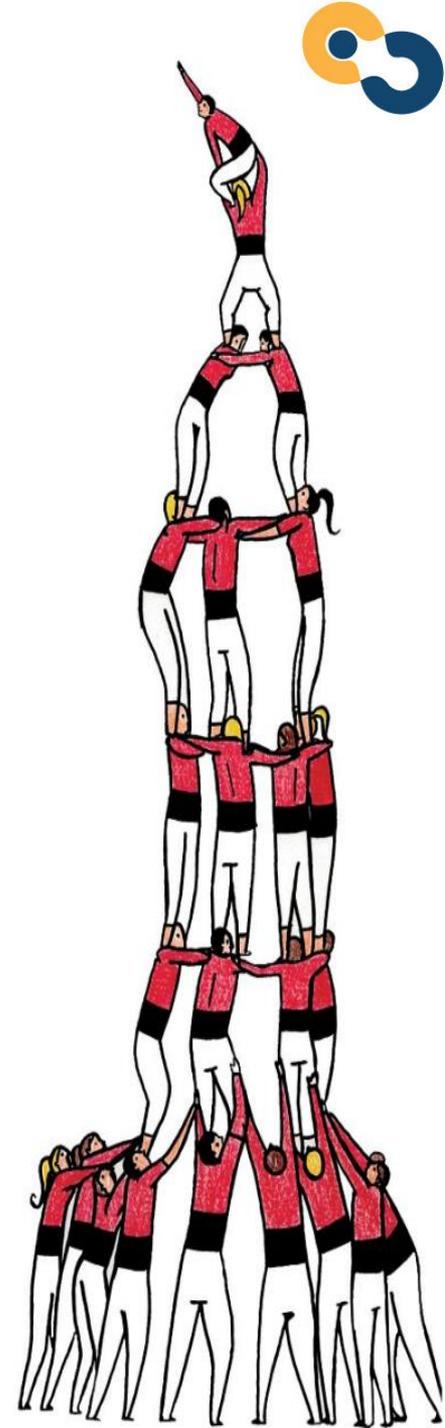


Interim Audit

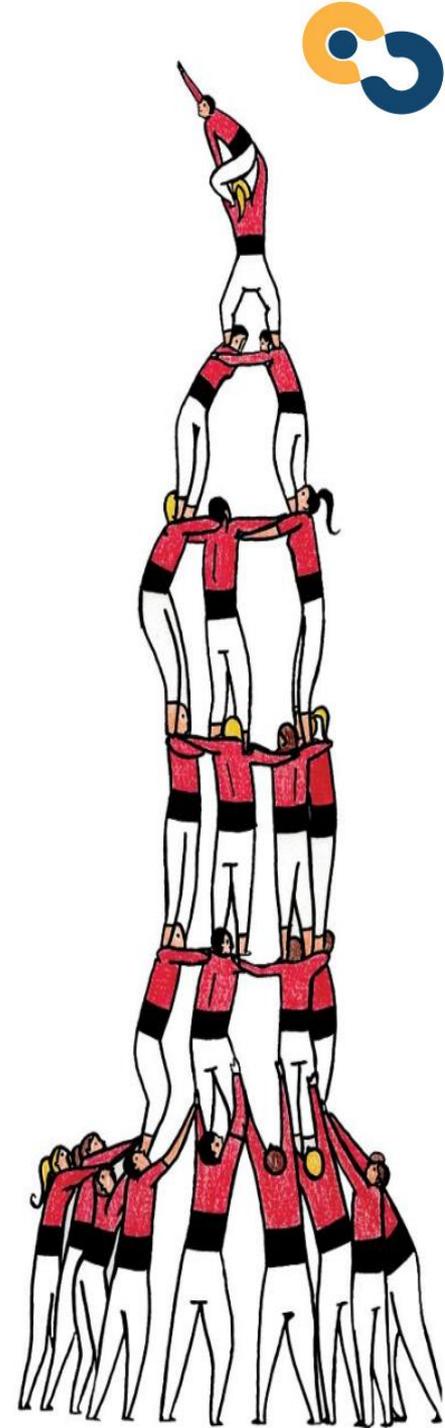


Interim Audit

- End of year 2 of Accreditation
- Review focus on how quality management is functioning:
 - Evidence of audits
 - QM review
 - SOP review
 - Etc...
- Based on standards
- May result in on-site visit



For your information



Fees – effective 17th April 2017



Inspection Fees per area	Full fees	Discounted fees for EBMT members
1 Area	€19,500	€9,750
2 Areas	€24,360	€12,180
3 Areas	€29,200	€14,600
Supplementary fee per each additional site	€4,000	€2,000
Discount for active inspector	15% - 1 active inspector 20% - >1 active inspector	15% - 1 active inspector 20% - >1 active inspector

- Areas are considered to be:
one (1) adult OR one (1) pediatric clinical site/unit
- one (1) collection site for marrow[#]
- one (1) for collection site for peripheral blood progenitor cells (apheresis)

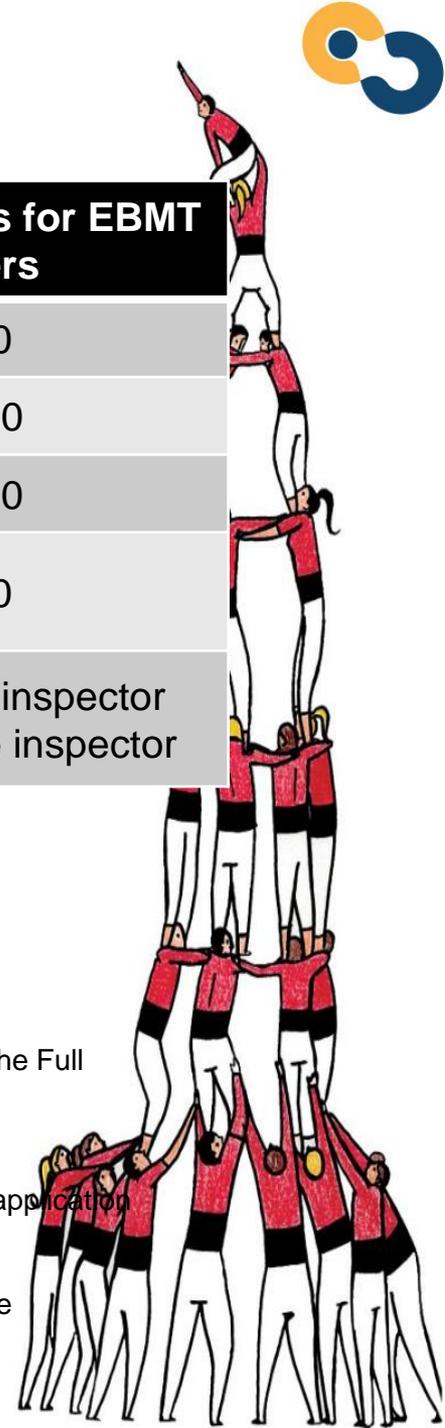
- one (1) cell-processing laboratory

[§]Where an application includes a clinical unit that **is** a member of the EBMT, a 50% discount is applied to the Full Fees.

For information on EBMT membership, please go to www.ebmt.org.

EBMT member centres should be up-to-date with their membership payments to the society at the time of application for accreditation.

Applications that do **not** include a clinical unit, e.g. Collection and Processing service, will be charged at the Discounted Fees rate.



Timing

Pre-audit documentation: 11.5 hr

Teleconference: 0.5 - 1 hr

Inspection: 1.5 days



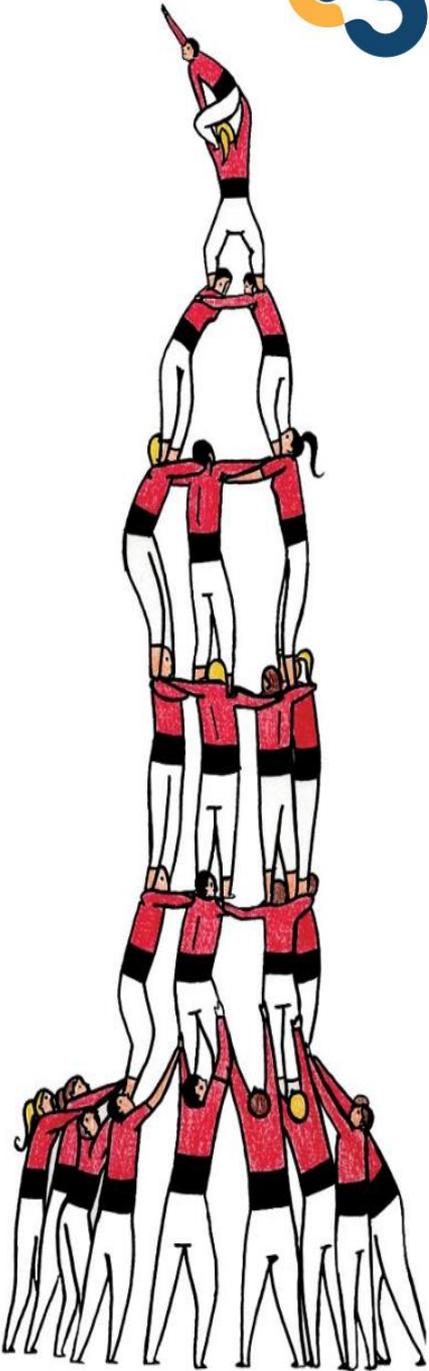
Inspection Report

Evidence of corrections

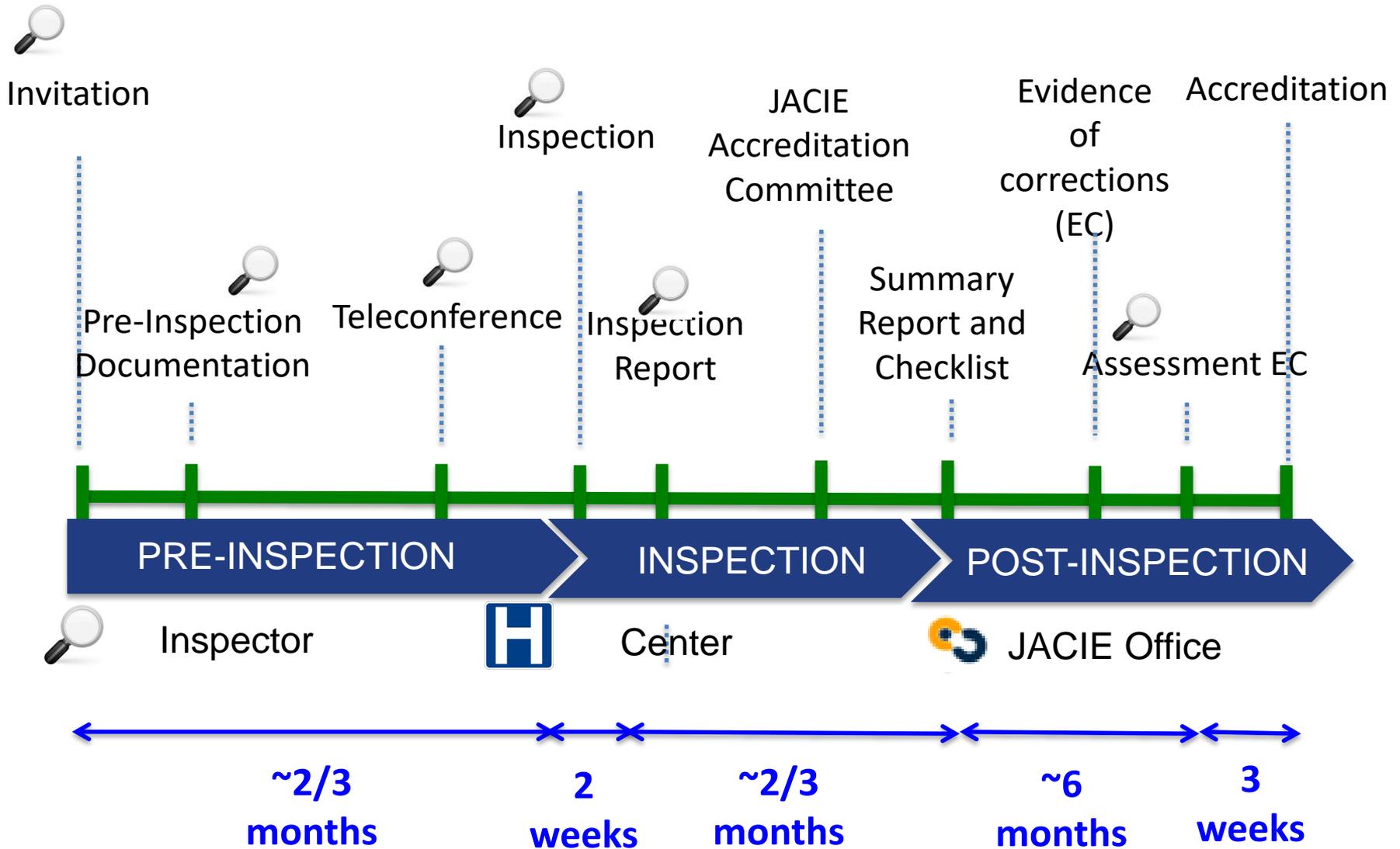
Interim Audit



JACIE Inspector

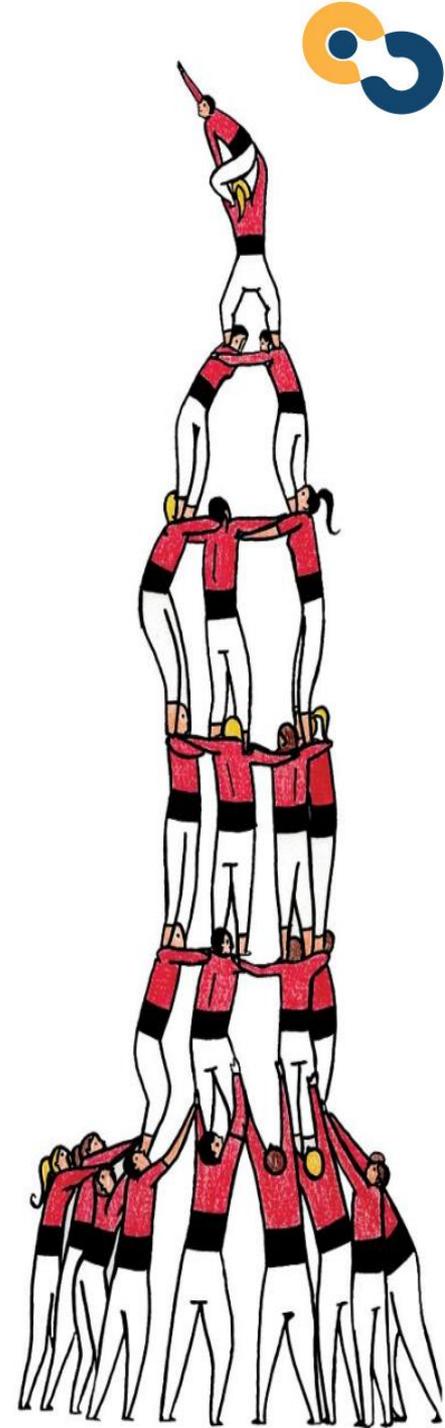


Timing



Summary

- Inspection
 - Team
 - 1,5 day
 - Plan, checklist, report
- JACIE Accreditation Committee
 - Expert Opinion
- Post-inspection
 - Review of corrections
- Accreditation
 - 4 years, certificate + letter
 - Certificate + letter
- Interim Audit
 - End of 2 year accreditation



- Thank you for listening
- Any questions?

