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THE JACIE ACCREDITATION PROCESS

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From Application To inspection

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Contents

1. Before submitting an application.
2. The application process.
3. The required pre-inspection documentation.
4. The actual inspection.

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Before submitting an application


Estrella Damm
BAUHAUS
Estrella Damm
BAUHAUS

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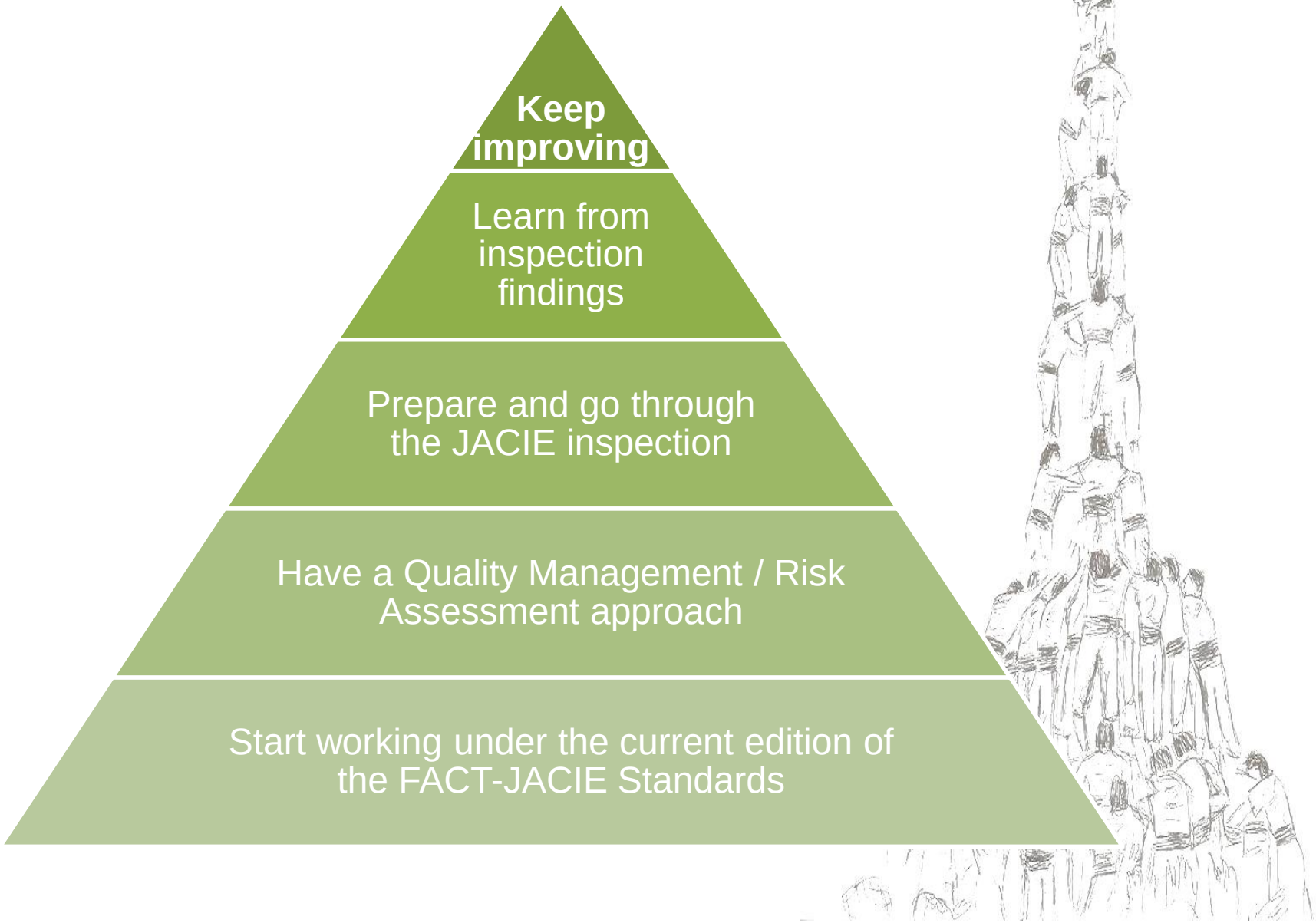

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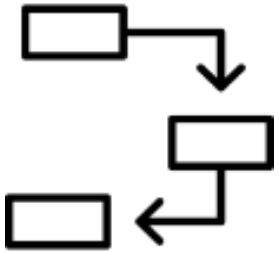
Before applying

INDICATORS

DOCUMENTATION

TRAINING

QM TEAM



STANDARDIZATION

AUDITS

Accreditation scope

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The application process

Documents needed

Application form

- Scope
- Structure
- Size
- Team organization

Checklist

First-time Applicants Only!

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The Checklist

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Part B: Clinical				Inspector: All items compliant?		Auto-complete	Definitions
IEC	07ref	7 standard	Applicant's assessment	Source of evidence and explanatory text	Inspector's Assessment	Inspector's Comments *(support your answers with additional information)*	Accreditation Committee comments
	B1	GENERAL	BLANK CELL	BLANK CELL	BLANK CELL	BLANK CELL	BLANK CELL
	B1.1	The Clinical Program shall consist of an integrated medical team that includes a Clinical Program Director(s) housed in a defined location(s).	Compliant	REF - SOP - 001 01	Compliant		
	B1.1.1	The Clinical Program shall demonstrate common staff training, protocols, Standard Operating Procedures, quality management systems, clinical outcome analyses, and regular interaction among all clinical sites.	Compliant	REF - SOP - 001 01	Non-compliant	Missing SOP	
	B1.2	The Clinical Program shall use cell collection and processing facilities that meet FACT-JACIE Standards with respect to their interactions with the Clinical Program.	Partially compliant	REF - SOP - 001 01	Partially compliant	SOP not complete	
IEC	B1.2.1	If the Clinical Program or an intermediary facility receives cellular therapy products directly from a third-party provider, the following responsibilities shall be defined, at a minimum, by a written agreement:	BLANK CELL	BLANK CELL	BLANK CELL	BLANK CELL	BLANK CELL
IEC	B1.2.1.1	Traceability and chain of	Compliant	Please indicate here			

... Part B Clinical 7 | QM - Part B 7 | Part B MED-A audit forms | Part CM Bone Marrow 7 | QM - Part CM Bone Marrow 7 | Part C Apheresis 7 | QM - Part C Apheresis 7

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Next steps

Quotation
Agreement signed
Invoice
Pre-audit documentation

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The required pre-inspection documentation

Pre-inspection documents

- SOPs
- Staff training and qualifications
- Licences and authorizations.
- QM Manual.
- QMS evidence.
- Transplant activity.
- Consent forms.
- Sample labels.
- Plans or maps.
- Third party agreements.

WHAT?

WHO?

WHEN?

HOW?

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The actual inspection

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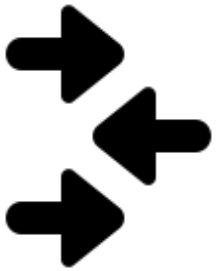
The inspectors

LANGUAGE
AND
AVAILABILITY



NO CONFLICT
OF INTEREST

TEAM
LEADER

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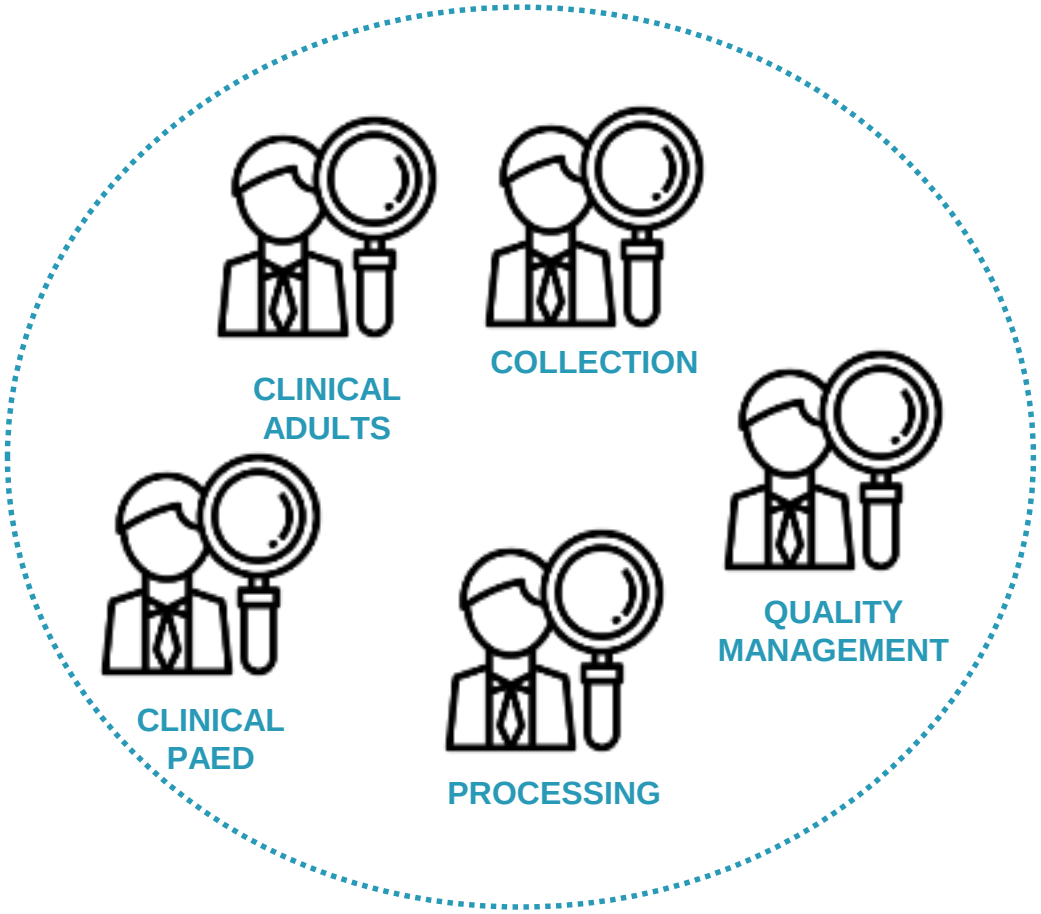
Inspection team



OBSERVER

FACILITATOR

Inspection duties

The applicant

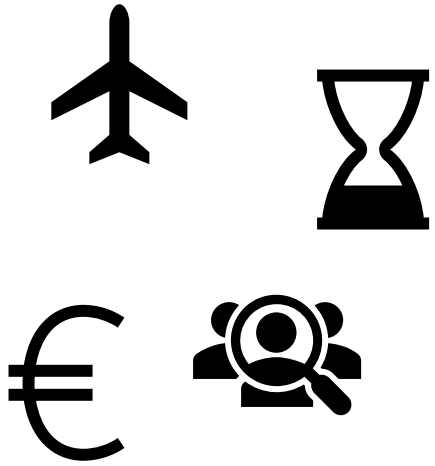
- Logistics
- Staff
- Private meeting rooms
- Possible process demo
- Documentation available

The inspectors

- Teleconference
- Interviews
- Prepare documentation
- Timetable
- Start working on the checklist

Logistics

- Travel agency preferred
- Arrival time
- Perdiem 80 euros per day (3 days)
- Inspector availability



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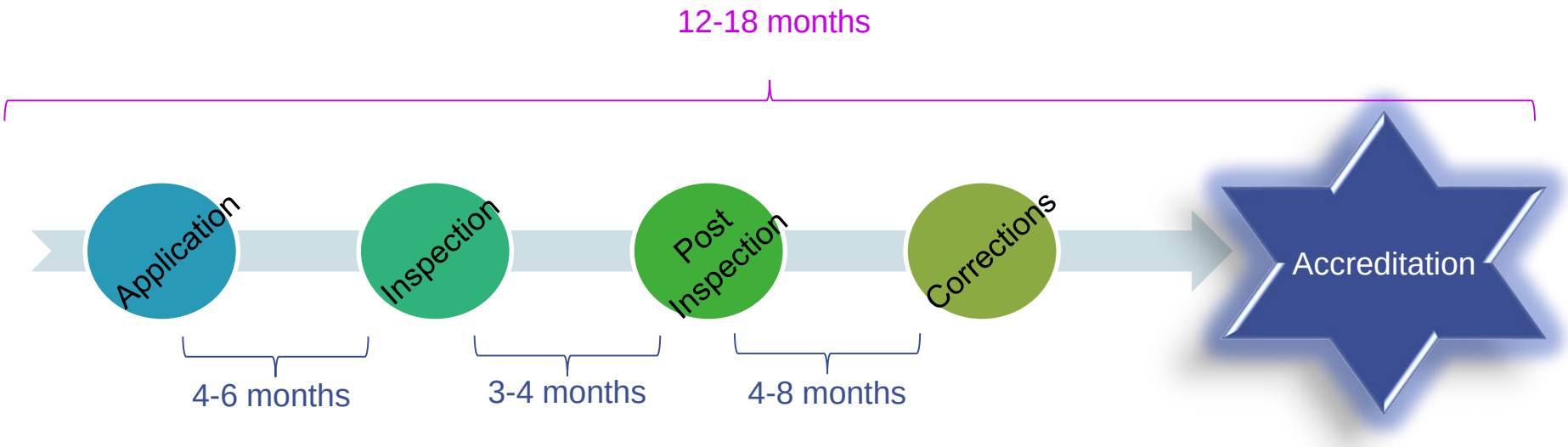
Timeline



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Time variables

- Amount of applications received
- Inspector availability
- Timely replies of inspectors
- Report turnaround and quality of reports
- Timely replies and corrections from the centre

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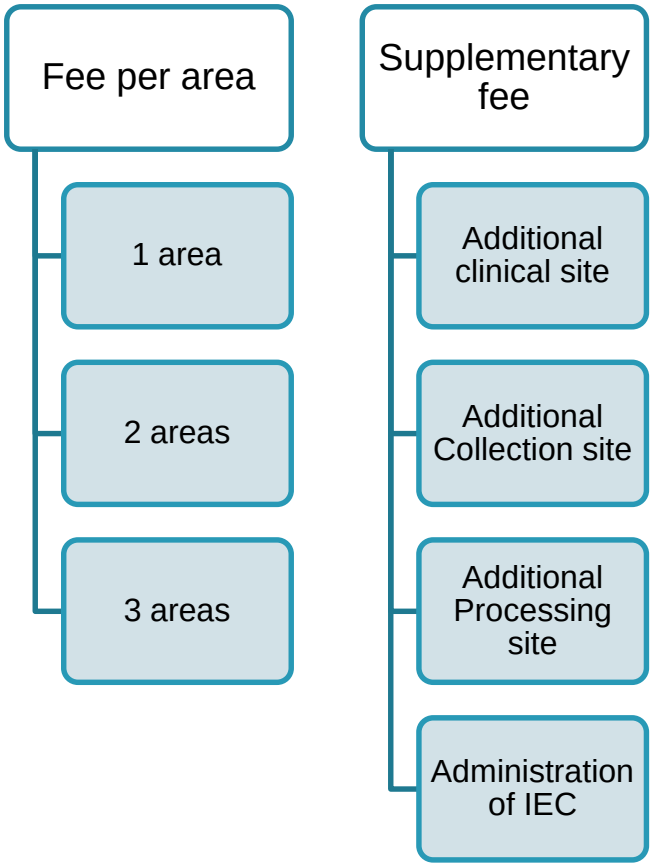
Accreditation fees



Discount

- EBMT Members **50%**
- 1 active inspection **15%**
- > 1 active inspector **20%**

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Summary

- Before applying
- Timeline and stages
- Roles and responsibilities before and during inspection