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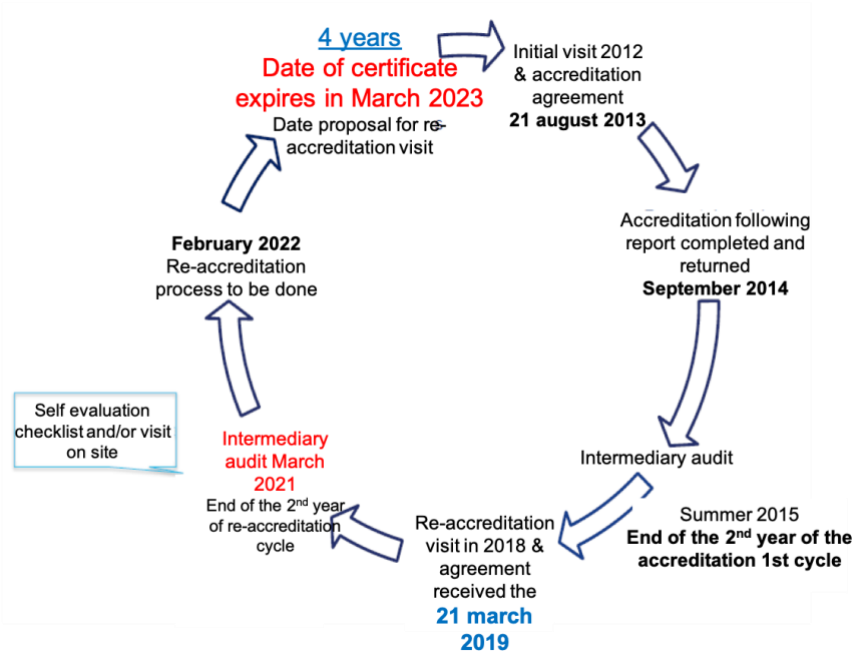
Summary of external evaluation

ASSISTANCE PUBLIQUE - HÔPITAUX DE PARIS (APHP) - Marrow and haematopoietic stem cell transplant programme

The departments involved in the JACIE programme:
Biotherapy: - The Therapeutic Haematology Unit (THU) - The Laboratory of Cell and Gene Therapy (LTCG)
Clinical departments: Adult Haematology and Paediatric Haematology Rheumatology Unit (PHRU)
Standard : Joint Accreditation Committee ISCT-Europe & EBMT (JACIE)
INTERIM AUDIT JACIE CHECKLIST 6.01 th edition - 16/08/2018 Issued by the JACIE Accreditation Office
Date audit : Mars 2021
Organization: Joint Accreditation Committee ISCT-Europe & EBMT (JACIE)

The accreditation cycle :



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Evaluation phase: Intermediate audit (End of the 2nd year of the accreditation cycle (self-assessment checklist)

The expectations of the audit:

Regulatory authorizations
Data on activity (number of transplants of each type performed in last 12 months)
Elements of the teams' files (medical & paramedical and support services, quality engineer)
Training and traceability authorizations
Interfaces (existing agreements)
QMS

The parts of the standard concerned by the audit:

•01 General documentation (Service & referral organization charts, QAM, Plans)
•02 Part B Clinical (Clinical services)
•03 Part C Collection (Hemapheresis)
•04 Part D Processing (LTCG)

1- Summary of the management system

The organisation of the transplant programme is formalised and structured around a process map:
- quality management process
- operational or implementation process,
- support process

The dynamics of continuous improvement are in place, allowing the development of the quality policy and the continuous improvement of the JACIE quality approach. The aim of this dynamic is to measure the relevance and effectiveness of the QMS with a view to its continuous improvement.

This organisation is based on a quality management system which is implemented through a documentary system that centralises the common procedures created, validated and approved.

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2- Assessment of the findings:

The availables answers:

- Compliant (where all aspects of the standard are met)
- Partially compliant (where some but not all aspects are met)
- Non-compliant (where none of the aspects are met)
- Not applicable (where the standard is not applicable to specific activity in the applicant facility or programme.

Part B : Clinical

Ref.	Standard	Applicant's assessment	Inspector's Assessment
B.03.10	**QUALITY MANAGER**	BLANK CELL	BLANK CELL
B.03.10.03	The Clinical Program Quality Manager shall participate in ten (10) hours of educational activities related to cellular therapy and/or quality management annually at a minimum.	Partially compliant Training needs for cell therapy activities	Partially compliant
B.03.10.04	Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation.	Partially compliant Training needs for cell therapy activities	Partially compliant

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Part D: Cell Processing

Inspector: All items compliant?
No

Standard	Applicant's assessment	Inspector's Assessment	Inspector's Comments *(support your answers with additional information)*
PERSONNEL			
PROCESSING FACILITY DIRECTOR			
The Processing Facility Director shall participate in ten (10) hours of educational activities related to cellular therapy annually at a minimum.	Partially compliant	Partially compliant	No proof of educational activities has been updated since 2017 (CV, educational passport and JACIE follow-up form)
Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation and processing.	Compliant	Partially compliant	Although the Processing Facility Director is the head of the biotherapy department, no proof of educational activities has been updated since 2017
PROCESSING FACILITY MEDICAL DIRECTOR			
The Processing Facility Medical Director shall participate in ten (10) hours of educational activities related to cellular therapy annually at a minimum.	Partially compliant	Partially compliant	No proof of educational activities has been updated since 2017 (CV, educational passport and JACIE follow-up form)

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Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation and processing.	Compliant	Partially compliant	Although the Processing Facility Medical Director is the head of the cell therapy unit, no proof of educational activities has been updated since 2017

Part D: Quality Management

Inspector: All items compliant?
No

Ref.	Standard	Applicant's assessment	Inspector's Assessment	Inspector's Comments *(support your answers with additional information)*
D.04	QUALITY MANAGEMENT			
D.04.06	The Quality Management Plan shall include, or summarize and reference, policies and procedures for establishment and maintenance of written agreements with third parties whose services impact the cellular therapy product.	Compliant	Partially compliant	Many of the agreement documents need to be updated.