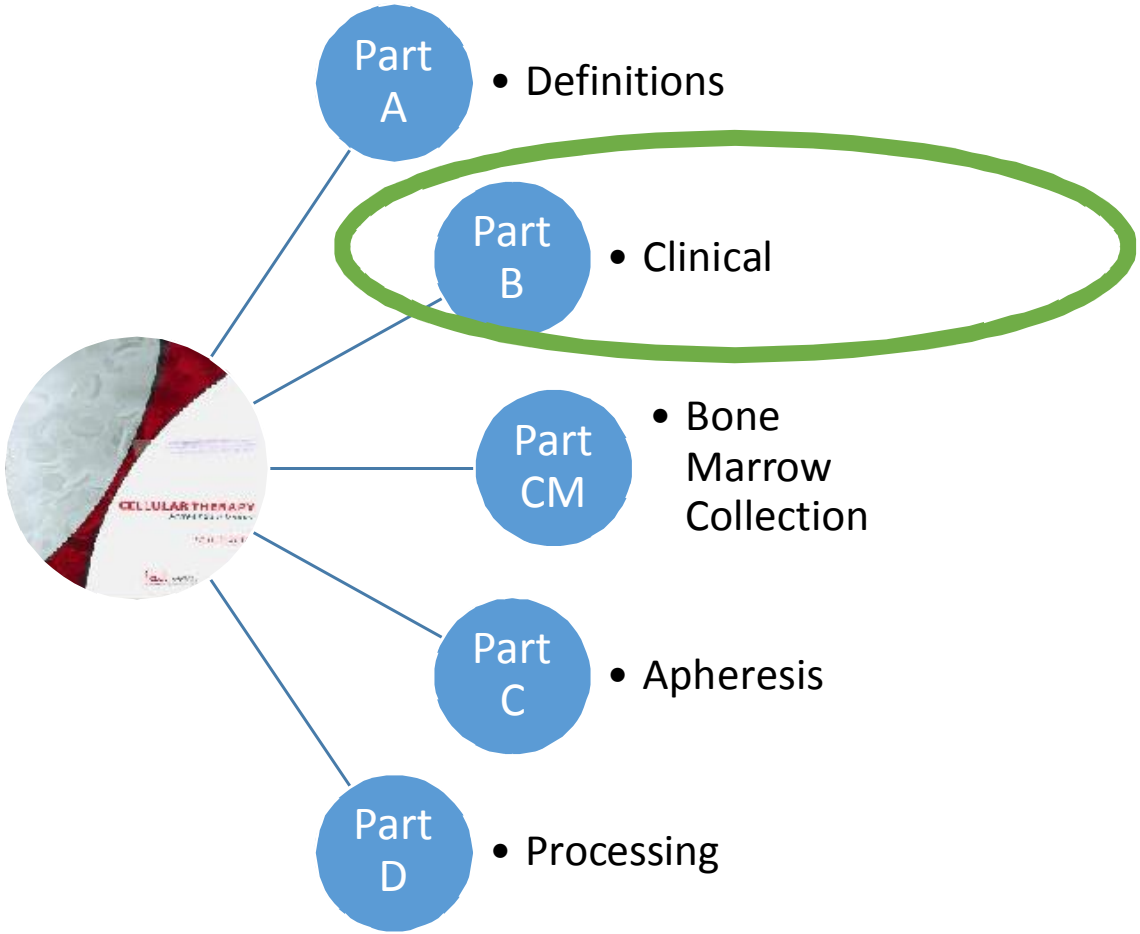
FACT-JACIE Standards

Clinical

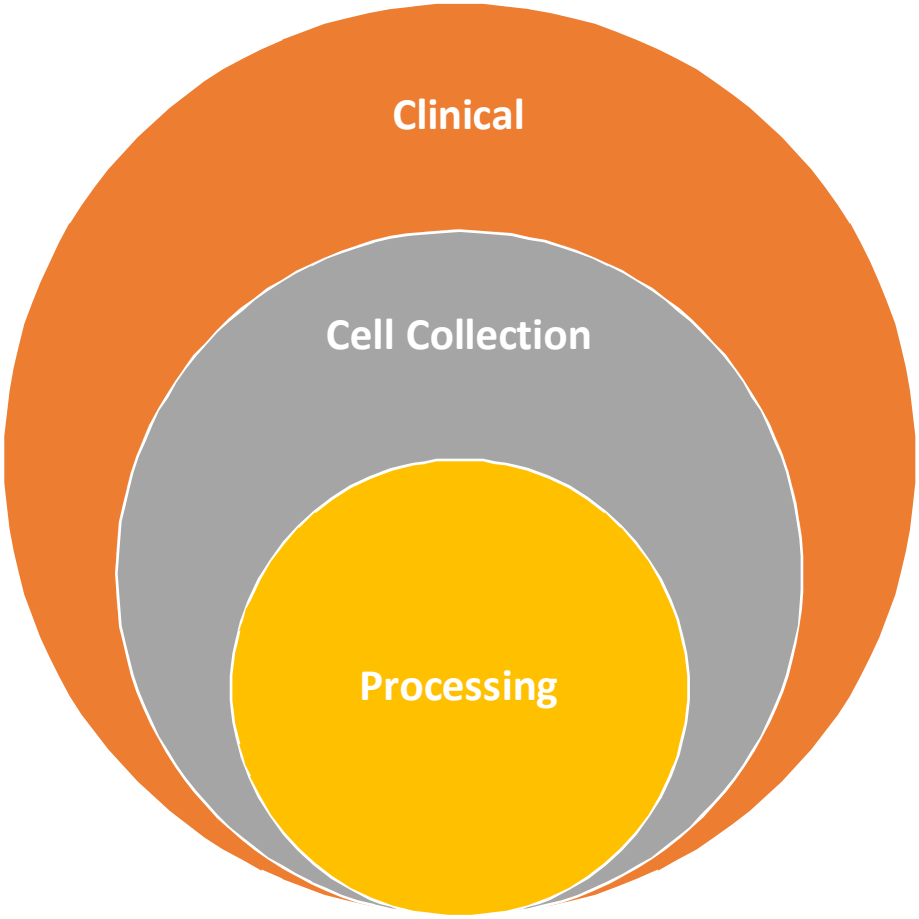
FACT-JACIE Standards



Clinical transplant programme

B1

B1 Transplant Programme



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Established

- Dedicated transplant team
  - Clinical Program Director(s)
  - one other physician trained and/or experienced in cell therapy and/or HPC transplantation
  - in place for at least twelve (12) months preceding accreditation

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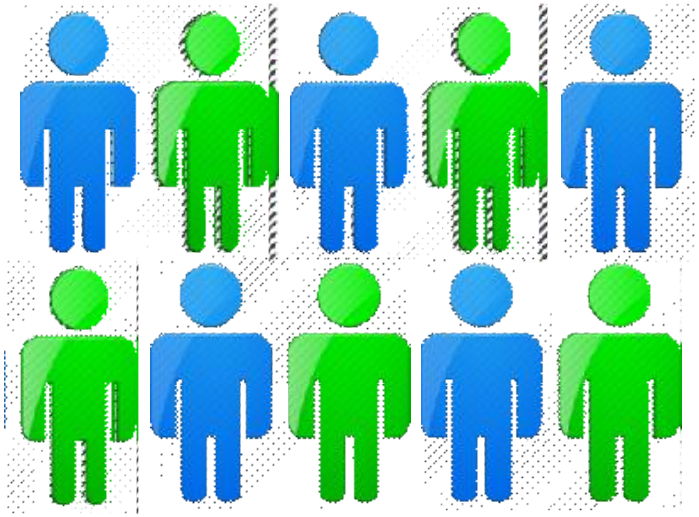
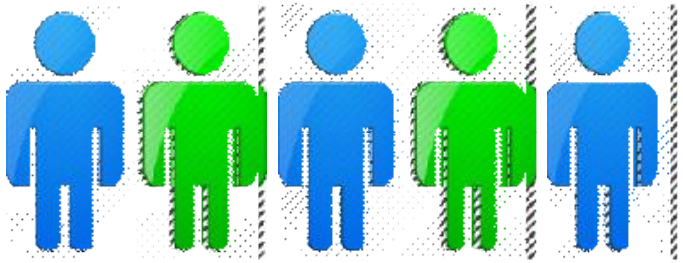
B1.5 Transplant activity

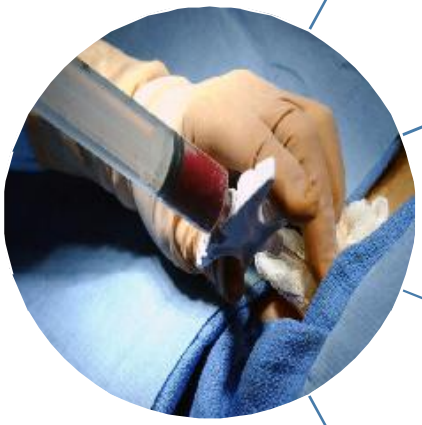
- Allogeneic (10)



- Autologous (5)



B1.5 Minimum transplant activity



Allo
- 10

Allo + Auto
- 10 + “1” - no min for autos

Auto
- 5

Adult + Ped
- Min 5 each population

MINIMUM NUMBER OF NEW PATIENTS FOR ACCREDITATION

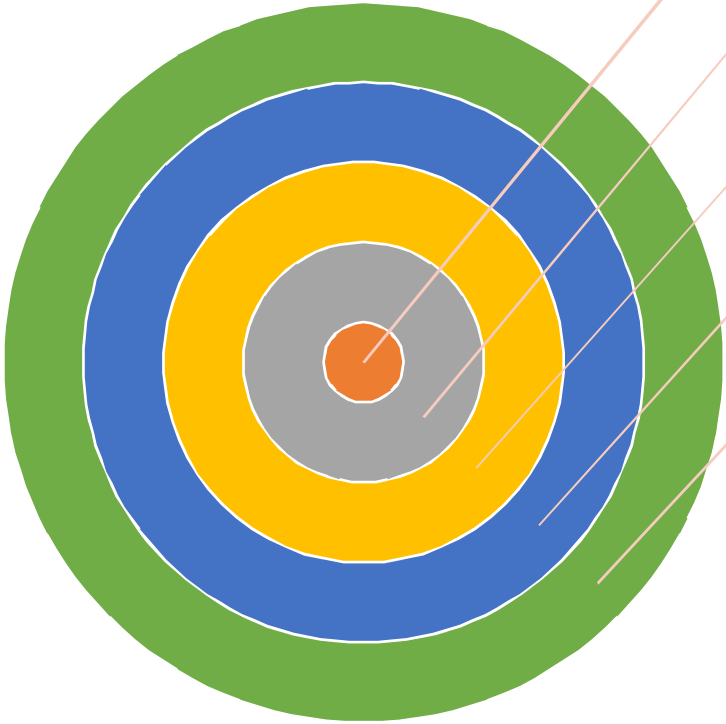
Clinical Programs shall transplant at least the following number of new patients[1] before initial accreditation and annually thereafter:

Transplant Population	Clinical Site(s)	Type of Transplant	Overall Minimum	Twelve (12) Months Prior to Initial Accreditation	Average Per Year Within Accreditation Cycle
Adult OR Pediatric (only one of these two)	Single Clinical Site	Allogeneic only[2]	30 allogeneic	10 allogeneic	10 allogeneic
		Autologous only	15 autologous	5 autologous	5 autologous
		Allogeneic and Autologous	30 allogeneic	10 allogeneic	10 allogeneic
	Multiple Clinical Sites	Allogeneic only[2]	15 allogeneic at each site	5 allogeneic at each site	5 allogeneic at each site
		Autologous only	15 allogeneic at each site	5 autologous at each site	5 autologous at each site
		Allogeneic and Autologous	15 allogeneic at each site 15 autologous at applicable sites[3]	5 allogeneic at each site 5 autologous at applicable sites[3]	5 allogeneic at each site 5 autologous at applicable sites[3]
Combined Adult AND Pediatric	Single Clinical Site	Allogeneic only[2]	15 adult allogeneic 15 pediatric allogeneic	5 adult allogeneic 5 pediatric allogeneic	5 adult allogeneic 5 pediatric allogeneic
		Autologous only	15 adult autologous 15 pediatric autologous	5 adult autologous 5 pediatric autologous	5 adult autologous 5 pediatric autologous
		Allogeneic and Autologous	15 adult allogeneic 15 pediatric allogeneic	5 adult allogeneic 5 pediatric allogeneic	5 adult allogeneic 5 pediatric allogeneic
	Multiple Clinical Sites	Allogeneic only[2]	15 adult allogeneic at each site 15 pediatric allogeneic at each site	5 adult allogeneic at each site 5 pediatric allogeneic at each site	5 adult allogeneic at each site 5 pediatric allogeneic at each site
		Autologous only	15 adult autologous at each site 15 pediatric autologous at each site	5 adult autologous at each site 5 pediatric autologous at each site	5 adult autologous at each site 5 pediatric autologous at each site
		Allogeneic and Autologous	15 adult allogeneic at each site 15 pediatric allogeneic at each site 15 adult autologous at applicable sites[3] 15 pediatric autologous at applicable sites[3]	5 adult allogeneic at each site 5 pediatric allogeneic at each site 5 adult autologous at applicable sites[3] 5 pediatric autologous at applicable sites[3]	5 adult allogeneic at each site 5 pediatric allogeneic at each site 5 adult autologous at applicable sites[3] 5 pediatric autologous at applicable sites[3]

Clinical unit

B2

Services required



Inpatient unit

24/7 physician available

Intensive care unit

Pharmacy 24/7

Outpatient unit

Also:

Renal support

24/7 access to CMV-appropriate / irradiated blood supplies

Supervised care when provided in other hospitals - must meet standards

Allogeneic:
Use EFI-accredited typing lab

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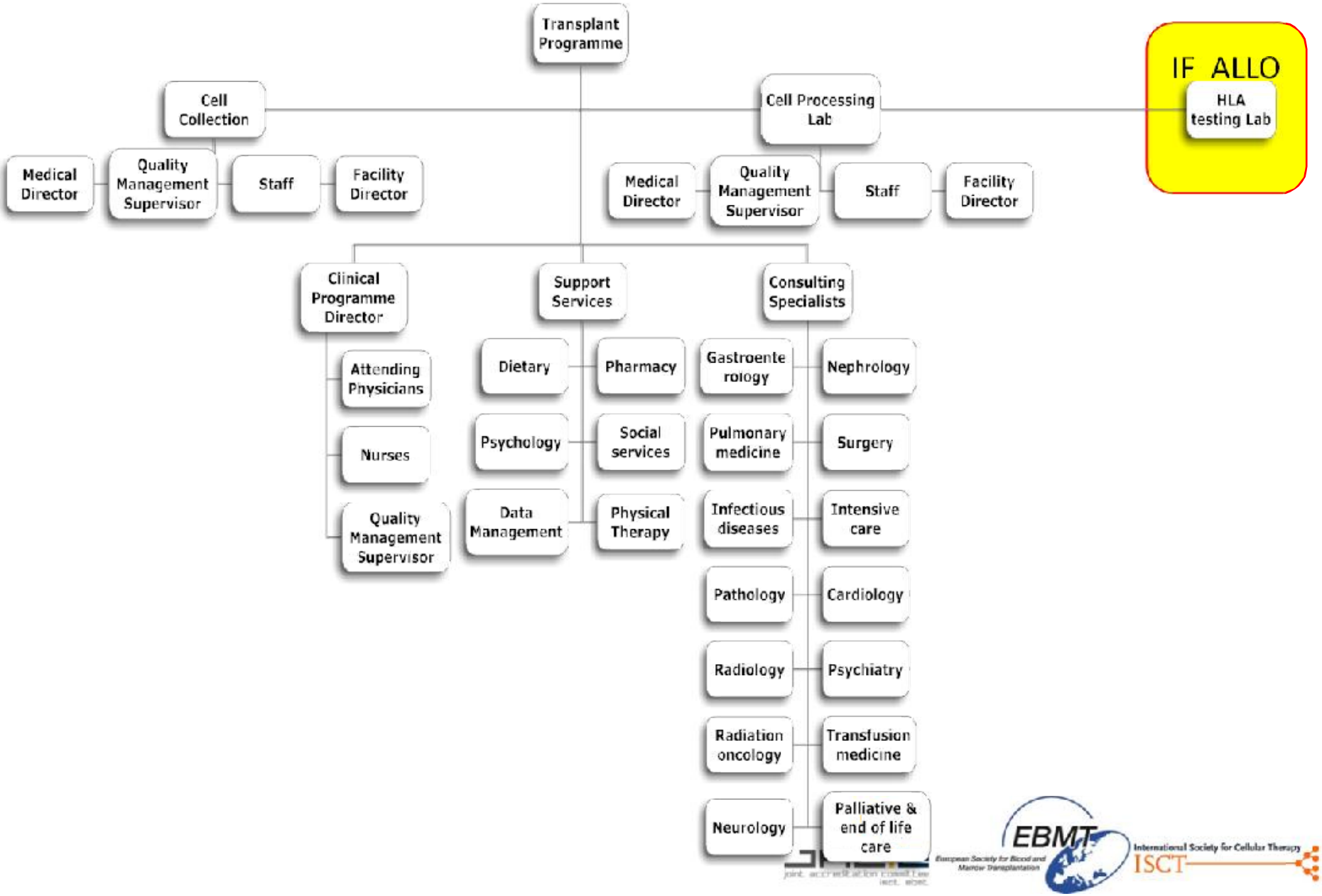
Personnel

B3

B3 Personnel



Pediatrics

- If you have pediatric patients, you must have physicians and nurses qualified and experienced in their care
  - B3.3.1
  - B3.6.2
  - B3.7.2
  - B5.7

B3.1 Clinical Programme Director - responsibilities

Procedures

Administrative operations

Quality Management Program of the Facility

Compliance with Standards and laws and regulations

Oversight of medical care provided by Clinical Program

Verifying the knowledge and skills the transplant team

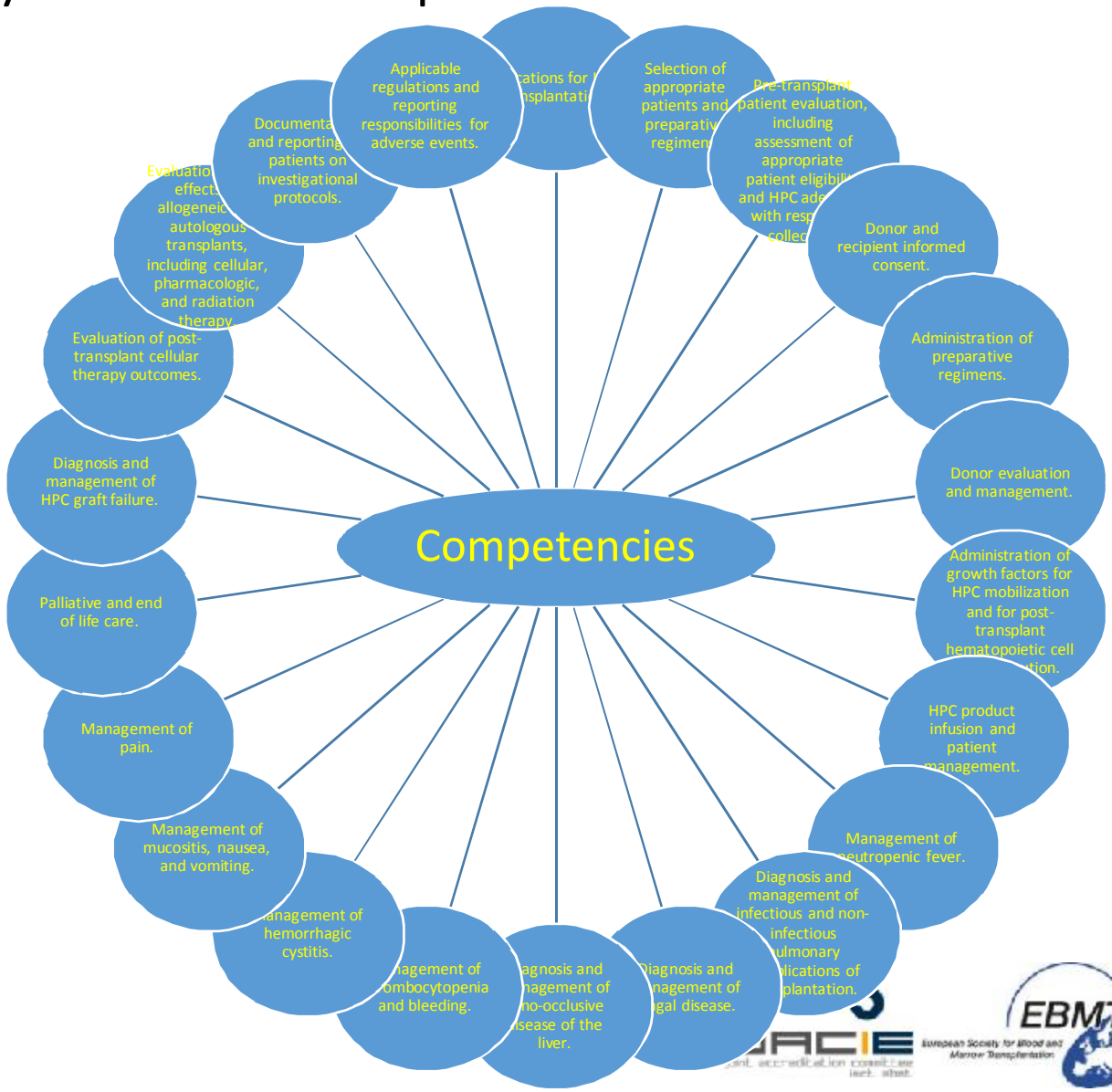
Bone marrow harvest

- Program shall have access to licensed physicians who are trained and competent in marrow collection and a marrow collection facility that meets these Standards.
  - CM1.4.1 **A minimum of one (1) marrow collection procedure** shall have been performed in the twelve (12) months preceding accreditation.

B3.2 Attending physicians

Licensed	Specialist	Education	Pediatrics
• Appropriately licensed to practice medicine in the jurisdiction of the Clinical Program	• Hematology • Medical Oncology • Adult or Pediatric Immunology or Pediatric Hematology/Oncology	• Participate regularly in educational activities related to the field of HPC transplantation	• Programs performing PEDIATRIC transplantation shall have a transplant team trained in the management of PEDIATRIC patients.

B3 Physicians' competencies



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B3.6 How many nurses?

- Adequate number of nurses experienced in the care of transplant patients
- Nurse/Patient ratio satisfactory to manage the severity of the patients' clinical status

Establish plan for:

- Increase nurse support when caseload increases
- Cover planned and unplanned absences
- **Training programme** in transplant care for hematology nurses

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B3.6 Nurses' Training/Competencies

1. • **Hematology/oncology patient care**, including an overview of CT process
2. • Recognition of cellular therapy **complications and emergencies** requiring rapid notification of the clinical transplant team
3. • Administration of **blood products, growth factors, CT products**, and other supportive therapies
4. • Administration of **preparative regimens**
5. • **Care interventions** to manage transplant complications
6. • **Palliative** and end of life care

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Quality management

B4

1. Plan

- Objective
- Questions and predictions (Why)
- The plan – who what where when

2. Do

- Do the Plan
- Document problems, observations
- Begin analysis of the data

3. Study

- Complete analysis of data
- Compare data to predictions
- Summarise the learning

4. Act

- What changes are to made now?
- What is the next cycle

- PDCA / PDSA
  - Plan
  - Do
  - Check/Study
  - Act

B 4.2 Quality Management Plan

an organizational chart of key personnel and functions

personnel education, experience, and training requirements for each key position

policies and procedures for development, approval, implementation, review, revision, and archival of all **critical processes**, policies, and procedures

a system for document control

policies and procedures for documentation and review of **outcome analysis and product efficacy**

policies, procedures, and a timetable for conducting, reviewing, and reporting audits

policies and procedures on the management of cellular therapy products with **positive microbial culture results**

B4.7 Documentation and review of outcome analysis and product efficacy

HPC products intended for hematopoietic reconstitution	• A process for documentation and review of **time to engraftment** following product administration

HPC products	• overall and TR morbidity and mortality at;
	  • **100 days**
	  • **1 year** after transplantation

Other cellular therapy products	• **criteria for product efficacy and/or the clinical outcome** shall be determined and shall be reviewed at regular time intervals.

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B4.7.2 Distributing data

WHAT?

Data on outcome analysis and product efficacy, including adverse events

WHEN?

"In a timely manner"

TO WHOM?

Entities involved in

- Collection
- Processing
- Distribution of the product

B4.9 Management of products with positive microbial culture results

1. Notification of the recipient
2. Recipient follow-up and outcome analysis
3. Follow-up of the donor, if relevant
4. Reporting to regulatory agencies if appropriate
5. Criteria for the administration of products with positive results

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B4.8 Audits

<u>HOW FREQUENTLY</u>?

"Periodically"

<u>BY WHOM</u>?

The Auditor should not be checking his own work

<u>WHY</u>?

To recognize problems, detect trends, identify improvement opportunities, implement corrective actions when necessary

What to audit?

Accuracy of data contained in Minimum Essential Data-A Forms of the EBMT

Donor screening and testing

Minimum audits

Verification of chemotherapy drug and dose against the orders and the protocol

Management of cellular therapy products with positive microbial culture results

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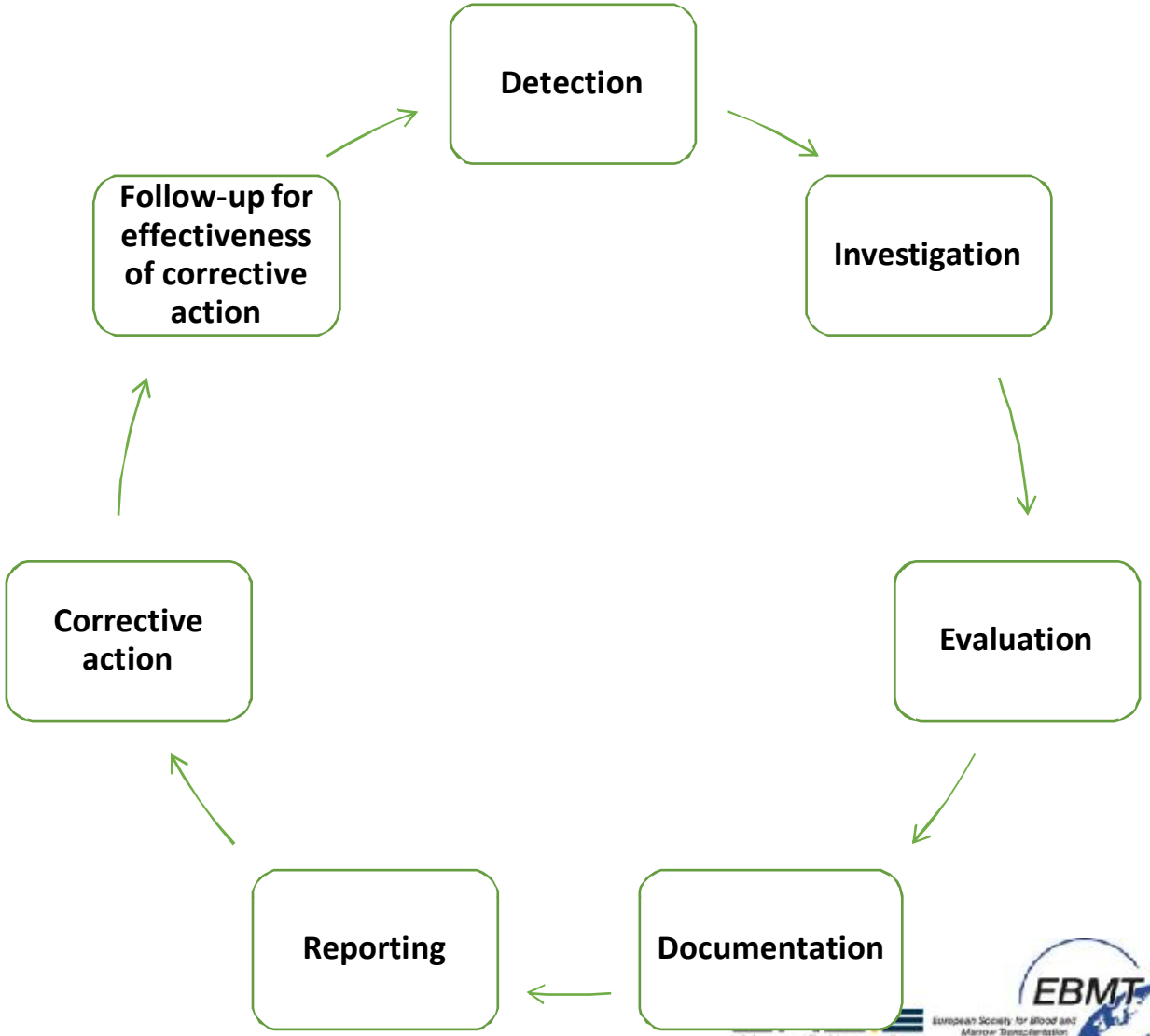
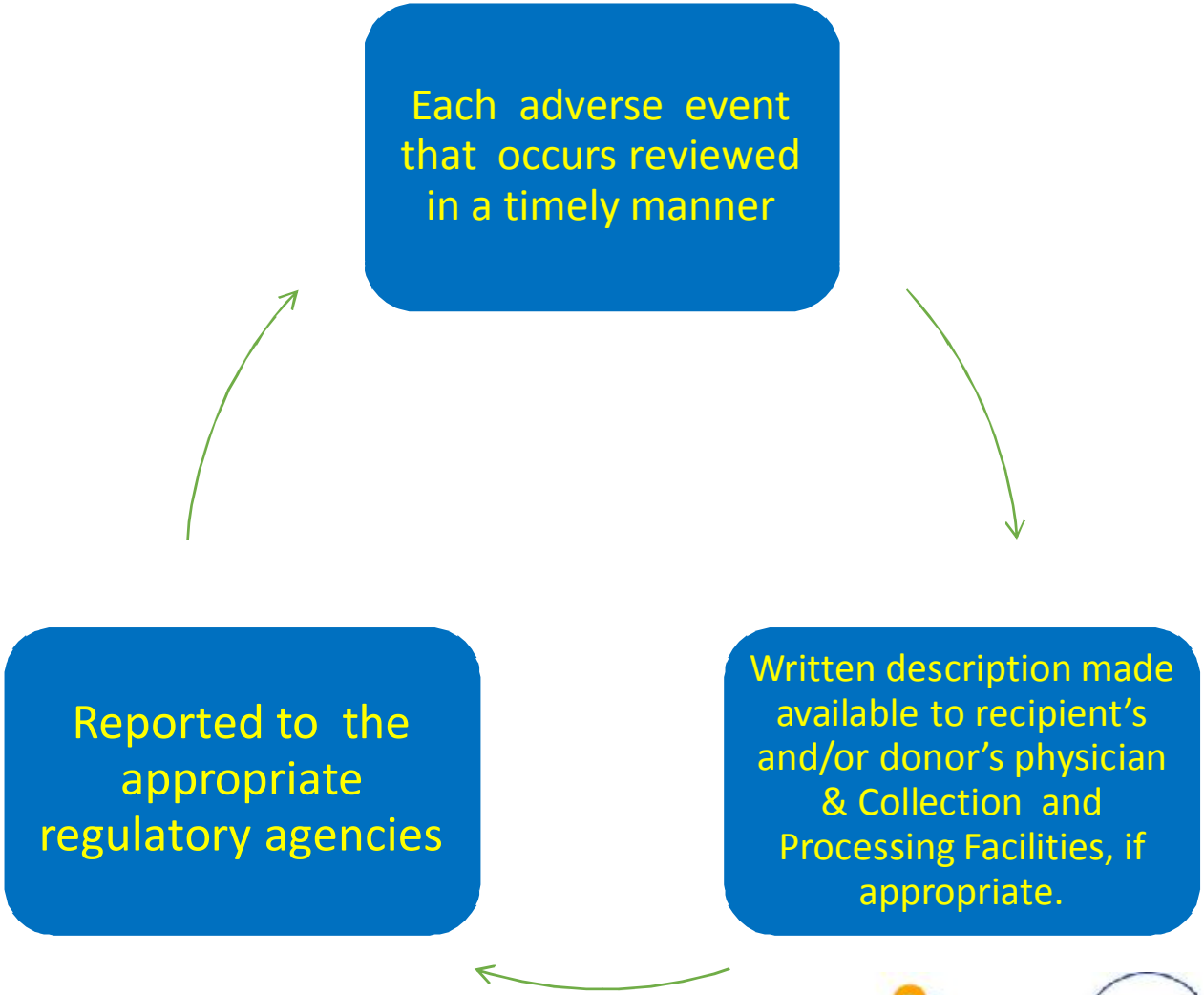
B4.10 Policies and procedures for errors, accidents, adverse events, biological product deviations, and complaints



B4.10 Adverse Events



B4.10.5 Deviations

Planned

- Pre-approved by the Clinical Program Director

Unplanned

- Reviewed by the Clinical Program Director or designee

From which procedures?

- critical aspects of operations and management:
  - Donor/recipient evaluation, selection, and treatment,
  - Administration of preparative CT and HPC products, incl. exceptional release…

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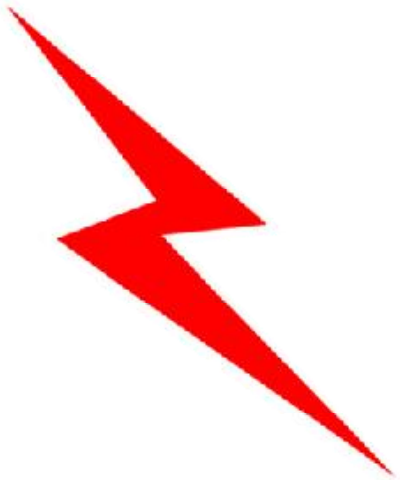
B4.12 Disaster / Emergency

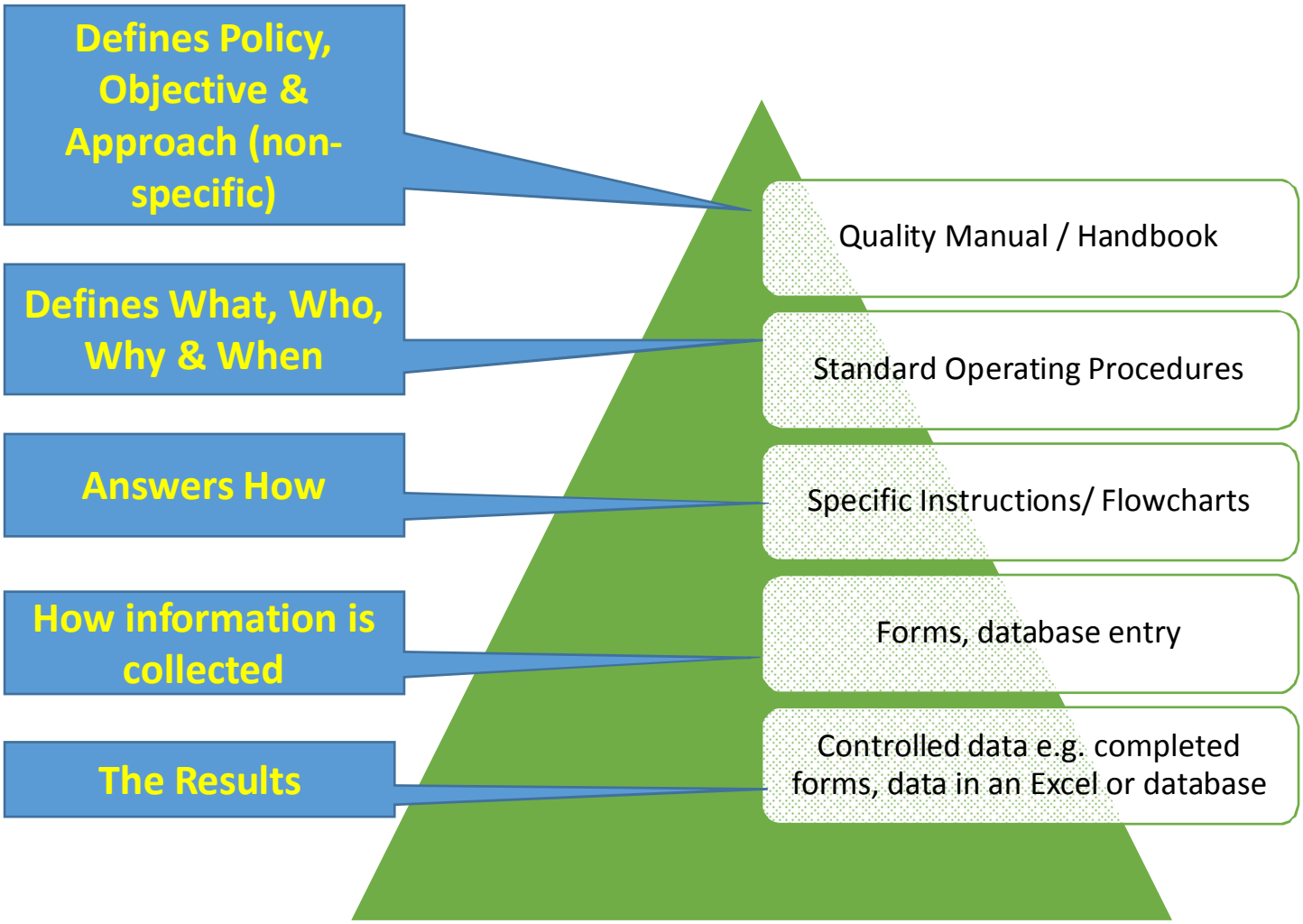


- Contingency plan for electrical failure
- Hospital emergency plan
  - Supplement for BMT-specific aspects e.g. rescue of stored cell products

Policies & procedures

B5

B5 Document hierarchy



B5.3 SOP content

- Unique identifier and title
- Objectives
- Equipment and supplies used
- Acceptable end-points and the range of expected results
- Stepwise description
- References
- Documented approval
- Documented approval of each procedural modification

B5 Procedures (SOPs)

- Donor and recipient evaluation, selection, and treatment
- Donor and recipient confidentiality
- Donor and recipient consent
- Infection prevention and control
- Facility management and monitoring
- Disposal of medical and biohazard waste
- Emergency and disaster plan, including the Clinical Program response
- Administration of blood products
- Administration of HPC and other cellular therapy products, including exceptional release
- Administration of the preparative regimen

Use your SOP Manual and SOP!

- B5.4 Copies of Standard Operating Procedures relevant to processes being performed, **shall be readily available to the facility staff**.
- B5.5 **All personnel in the facility shall follow** the Standard Operating Procedures related to their positions.
- B5.6 **Review and/or training by a staff member shall be documented** before the staff member is allowed to perform new and revised policies and procedures.
- B5.7 **There shall be a process to address age-specific issues** in the Standard Operating Procedures, as appropriate.

Document management

- Clear review and approval process
- Min. 2-yearly review
- Associated training before implementing amended/new procedures
- Critical procedures available in applicable area
- Electronic system is acceptable
  - Consider how to operate in case of system failure

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Therapy administration

B7

B7 Therapy Administration

1

- Verify availability and suitability of donor or cellular therapy product prior to initiating the recipient's preparative regimen

2

- Clinical service - notify the Processing Facility prior to requesting a cryopreserved cellular therapy product from a cord blood bank or registry

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B7.2

Policy addressing safe aadministration of the preparative regimen

B7.2.1 Chemotherapy

Policy for administration of chemotherapy

Written order from physician

Orders verified & documented by physician

Pharmacist verifies doses against protocol or standardized regimen

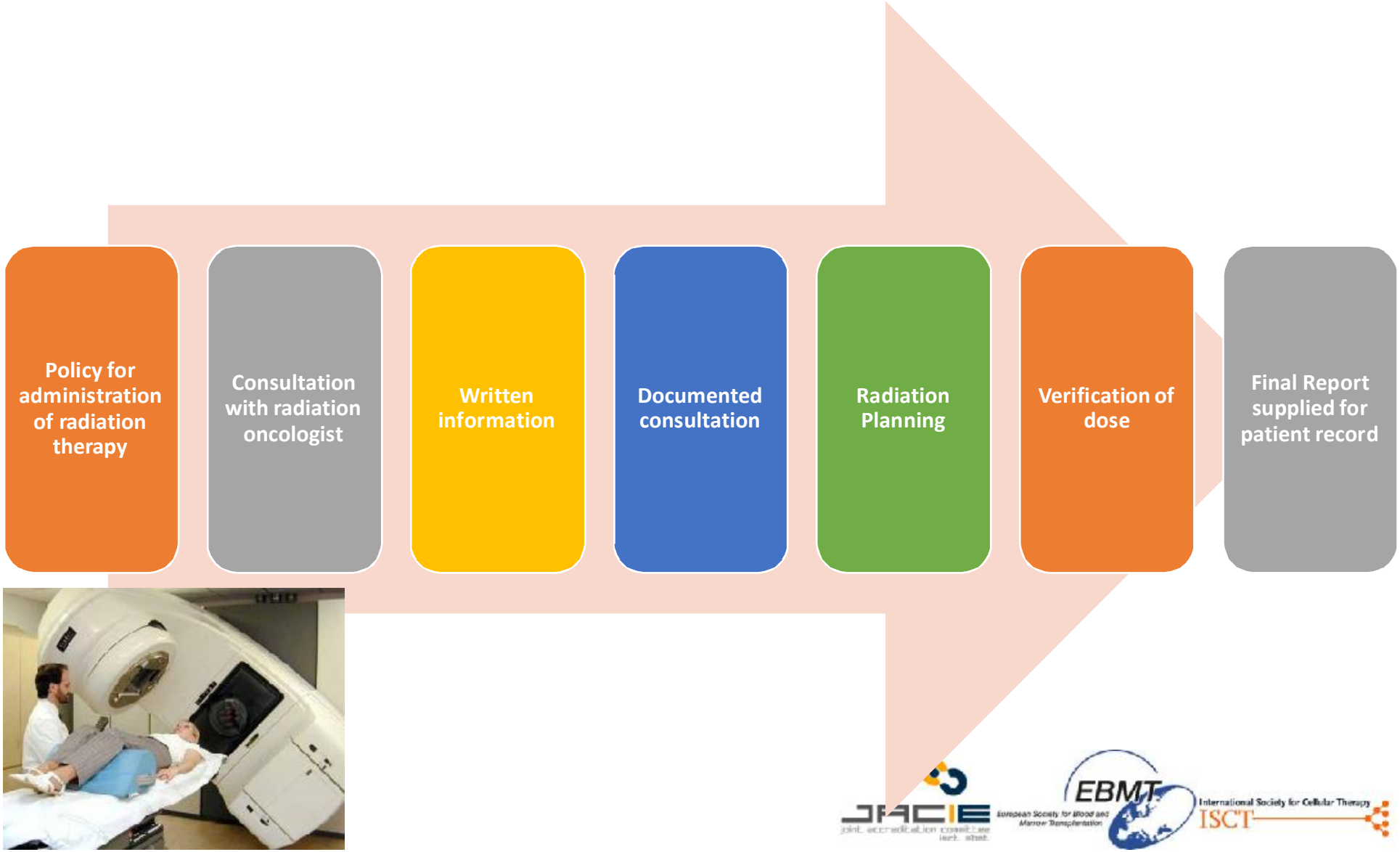
2 persons verify drug & dose against orders & protocol

2 persons verify identity of patient

B7.2.1.1 Treatment orders

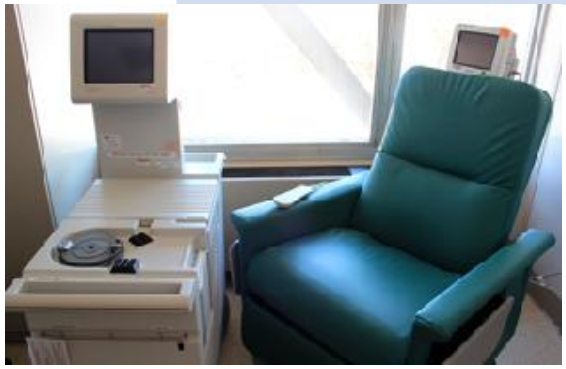
- Include
  - Height
  - Weight
  - Specific dates
  - Daily doses (if appropriate)
  - Route of administration of each agent

B7.2.2 Radiation Therapy



B7.3 Extracorporeal photopheresis

- Policy for administration of ECP
- Consultation with ECP facility
- Written order from physician
- ECP performed according to SOP(s)
- Final Report supplied for patient record
- Review of outcomes and adverse events on annual basis



B7.4 Administration

Policy for administration of cellular therapy products

2 persons verify identity of recipient & product & order for administration

Documentation in patient medical record of the unit identifier and a copy of the distribution record

Clinical research

B8

B8 Clinical Research

- Standards establish framework for research
  - Legal compliance
  - Pharmacy support
  - Approval by relevant bodies e.g. Ethics Committee, Regulatory Agency
  - Consent requirements

Data management

B9

B9 Data Management

- The Clinical Program shall collect all the data <u>necessary to complete</u> the … CIBMTR TED or EBMT MED-A forms
  - No requirement to <u>report</u> but <u>strongly</u> recommended

CIC. ..... Unique Patient Number (UPN). ..... HSCT Date..... .... - .... - .....
yyyy mm dd

HSCT - Minimum Essential Data - A

First report - 100 days after HSCT

CENTRE IDENTIFICATION

EBMT Code (CIC): ....
CIBMTR Center # .....
Hospital: ..... Unit: .....
Contact person.....
Phone:..... Fax:.....
e-mail: .....

PATIENT DATA

Date of this Report: ..... - ..... - .....
yyyy mm dd
CIBMTR patient (recipient) Identification .....
Patient following national / international study / trial:
☐ Yes ☐ No ☐ Unknown
Name of study / trial ....
Unique Patient Number or Code: .....
Compulsory, registrations will not be accepted without this item

HSCT

Chronological number of HSCT for this patient? |___|
If >1, date of last HSCT before this one: ..... - .....-.....
yyyy mm dd
If >1, type of last HSCT before this one ☐ Allo ☐ Auto ☐ N/A

HSCT part of a planned multiple graft protocol?
☐ No ☐ Yes

Preparative (conditioning) regimen given?
☐ No (*Usually Paed Inherited Disorders only*) *CONTINUE TO P. 2*
☐ Yes

Was this intended to be myeloablative? *(allo only)*
☐ Yes ☐ No: Reason:
☐ Age of recipient
☐ Comorbid conditions
☐ Prior HSCT
☐ Protocol driven

Records

B10

B10 Records

What Records?
Quality control
Personnel training and competency
Facility maintenance & management
Complaints
Other general facility issues
Employee records
Patient and donor records
Research records

B10 Records

- Establish archive policy in line with regulations and laws
  - Minimum 10 years for
    - Research records
    - Patient / Donor records