

### Introduction

As **initial accredited centre** (JACIE v.6.01) we reviewed all procedures and processes to **implement** the requirements of the **JACIE v7 Standards**. Compliance with C.4.13 and D.4.13 directly followed the already established system of defined requirements for critical manufacturers, vendors, equipment, supplies, reagents, facilities and services and performed validations. The requirements of the **new text of B.4.13** were a challenge to consider whether other areas are also suitable for **the formulation of qualification plans**, not just for the marrow collection and processing or for the clinical procedures technical aspects only.

#### JACIE standards v7

B4.13 The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for qualification of critical manufacturers, vendors, equipment, supplies, reagents, facilities, and services.

B4.13.1 Critical equipment, supplies, reagents, and facilities used for the marrow collection procedure shall be qualified.

B4.13.2 Qualification plans shall include minimum acceptance criteria for performance.

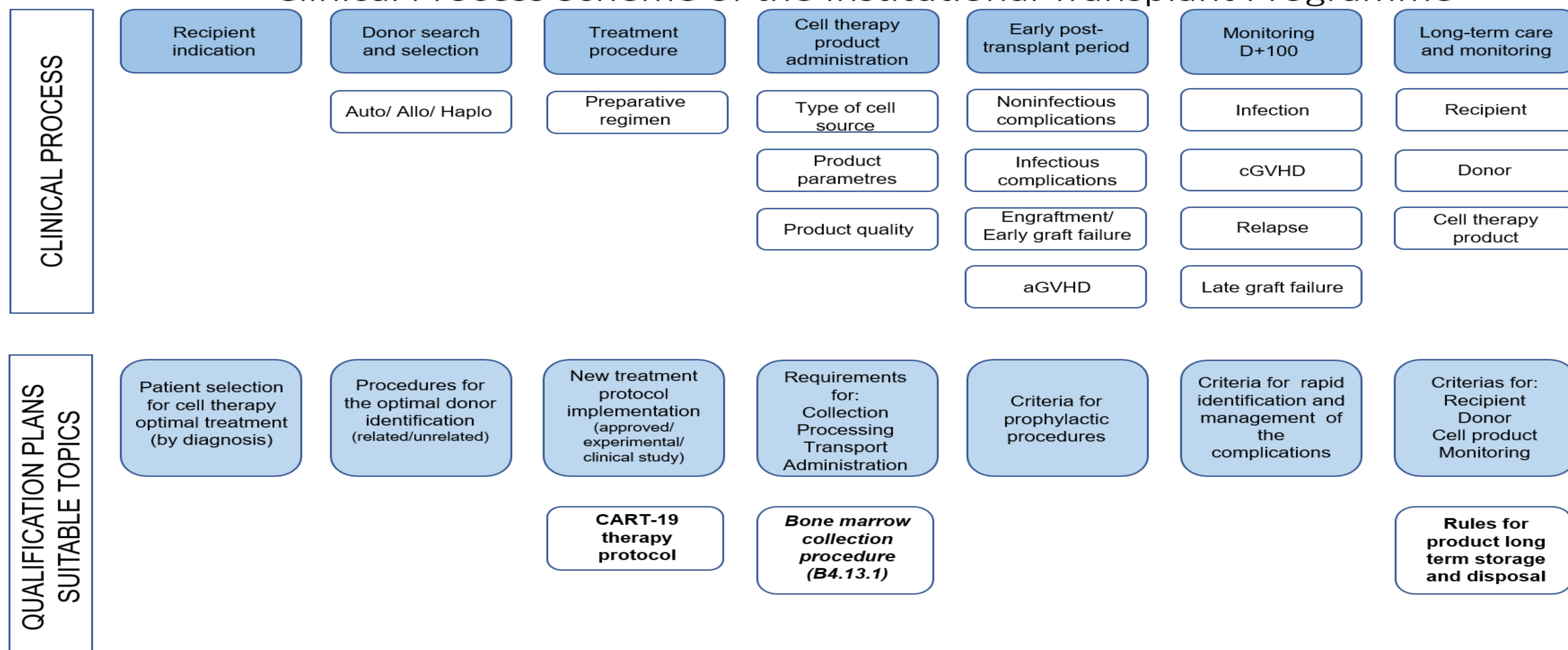
B4.13.3 Qualification plans, results, and reports shall be reviewed and approved by the Quality Manager and Clinical Program Director or designee.

**The qualification plan in the broader sense is the answer to the question „What must be done to...?“**

### Results

The Institutional Transplant Program **Process Diagram** was a suitable starting point for analysis of the potential qualification steps in the Clinical part.

#### Clinical Process Scheme of the Institutional Transplant Programme



We formulated a qualification plan for the **implementation of the new immunotherapeutic therapy** (CART-19/ Kymriah), where we defined the areas that need to be clarified, namely:

■ type of treatment - approved, recommended/ experimental ■ the guidelines and external information sources availability ■ cooperation with other workplaces and facilities ■ treatment indication and procedure (include SOP and records) ■ patient information ■ informed consents ■ technical equipment and support ■ personal education training and competency ■ product workflow (requirements of cell collection, products processing, storage and transport, disposal, product documentation and records) ■ patient specific risks and management of the complications ■ safety aspects (waste management, risks for staff) ■ related records and data management ■ quality management (e.g. internal audits checklist)

Further to the issued recommendations of the Czech Haematology Society, we proceeded to establish criteria for long-term storage of cryopreserved cell therapy products, which we have not yet clearly defined.

**Qualification plan for cell therapy product removal and disposal** includes:

**main criteria:** ■ death of the recipient ■ contraindications to transplantation ■ change in treatment strategy (non-transplant care, allogeneic transplantation instead of autologous transplantation, etc.) ■ omission of the medical need for the product storage (long-term remission of the disease after allogeneic transplantation) ■ exceeding the expiration date of the product ■ inability to unambiguously identify the product (damaged product designation).  
**secondary criteria:** ■ serious and documented doubts about the quality of the product (severe violation of the integrity of the cryovac, non-compliance with the required storage conditions – „cold chain interruption“) ■ insufficient dose of CD34+ cells or CFU-GM (for repeated transplants) ■ significant microbial contamination.

### Conclusion

Based on our experience, we believe that formulation of qualification plans for other areas, not required by JACIE standards, allow to optimize procedures description and documentation (SOP's structure and content, related records) and control processes (audit specific checklists) and enable better preparation of new activities, more effective internal controlling and better long-term adherence to daily practice with defined procedures. We want to use this approach also where the evaluation of established quality management shows us that there is higher probability of deviations or potential risks.

However, this is always based on the conditions, established procedures and control mechanisms specific to the centre.

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