DKMS

WE DELETE BLOOD CANCER

Qualification of Collection Centers

Agenda

01 Overview of a Workup Request

02 General requirements (WMDA Standard)

03 Specific requirements

04 Selection of a Collection Center

1. Overview of a Workup Request

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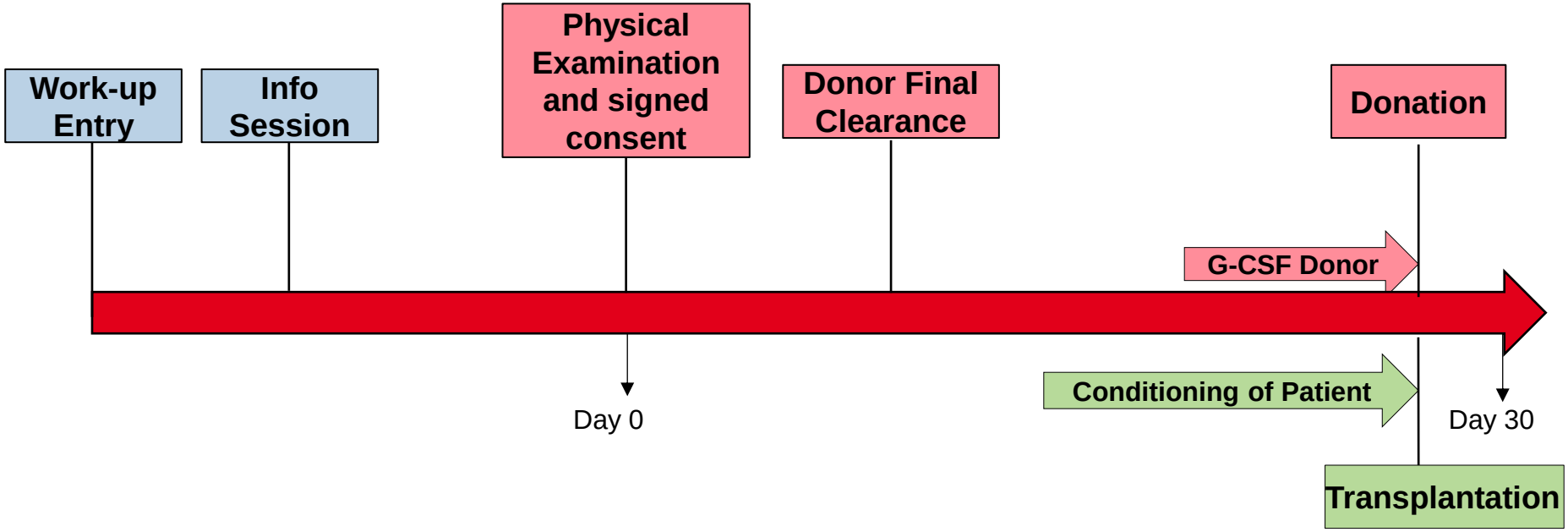
Overview



DC Task
CC Task
TC Task

2. General Requirements (WMDA / JACIE Standard)

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General Requirements

- Facility
- Collection Center Staff
- Donor Health & Eligibility
- Information Session & Informed Consent
- Study Requests / Samples
- Collection Procedure
- Product Identification & Handover
- Post Donation Care

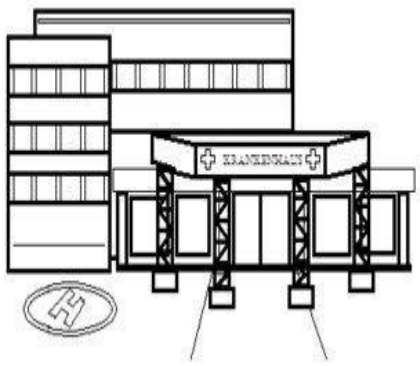
Facility

- The collection center (CC) must meet at a minimum the criteria mentioned in WMDA Standards, and national regulations and laws (WMDA 1.08, JACIE1.3.)
- The CC must be registered, licensed, or accredited by all relevant governmental authorities, and adhere to applicable national and international regulations (WMDA 8.01, JACIE1.3)
- The CC should have an appropriate insurance coverage for UDs and HPC collections (WMDA 3.10.1)
- The CC should have a plan to provide crisis response, business continuity and disaster recovery (JACIE CM5.1.13 & C5.1.19)
- The CC must provide daily intensive care and emergency coverage for UDs and must have an emergency phone with 24/7 availability (WMDA 8.02 ,JACIE CM2.6 & C2.7)

Facility

- The CC must have and maintain adequate and appropriate staff , resources, equipment, supplies, and pharmaceuticals to support its collection and associated management activities (WMDA 8.01 & 8.03, JACIE CM2.7 & C2.8)
- The CC must have a designated site for the management of collection activities, and a secure environment for confidential record storage that meets specific country requirements (WMDA 8.02, JACIE C11.1.2 & 11.1.4 & 11.2.1)
- The CC shall establish and maintain policies and/or procedures addressing all critical aspects of operations and management (WMDA 8.06, JACIE CM5.1.1.1-C5.1.13 & C5.1.1.1-C5.1.19)
- The CC must have controlled storage areas to prevent mix-ups, contamination, and cross-contamination of products (WMDA 8.06, JACIE C11.1.4)

General Requirements



Collection Center Staff

Donor Health & Eligibility

Information Session & Informed Consent

Study Requests / Samples

Collection Procedure

Product Identification & Handover

Post Donation Care

Collection Center Staff

- There must be a CC medical director or their designee who is a licensed or certified physician with postgraduate training in cell collection and/or transplantation according to national and registry specific regulations (WMDA 8.03, JACIE C/CM1.4 & C/CM3.1.1 & C 3.2.1)

- The CC medical director or their designee must have at least one year experience in HPC collection procedures or have performed or supervised at least 10 BM collection procedures within his/her career in case of an BM CC and/or 5 PBSC collections per year (WMDA 8.02, JACIE CM3.1.2.1- 3.1.2.8 & C3.2.2)

- The physician responsible for the collection must have experience in the field of stem cell collections (WMDA 8.03, JACIE CM3.3.1 & C3.4.1)

- CC staff (especially clinical personnel) that works with UDs must be experienced in the field of HPC collections (e.g. autologous, related donors) and/ or transplantations (WMDA 3.11.1, 3.12, 8.03, JACIE CM3.3.1, CM6.1 & C3.4.1, C6.1)

- The personnel working directly with UDs must be well trained in handling UDs and understand their special needs (WMDA 3.11.1, 3.12, 8.03, JACIE CM3.3.1, CM6.1 & C3.4.1, C6.1)

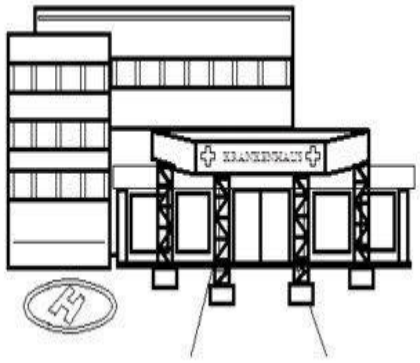
Collection Center Staff

- The PBSC CC staff must be trained in the administration of mobilizing agents to UDs; experienced in the collection procedure and handling of HPC apheresis products; well trained in the management of apheresis of UDs including those with central venous catheters (CVC), if CVCs are applied at the center and need to be used according to WMDA Standards (WMDA 8.05, JACIE C3.4.1, C5.1.4, C8.10, C8.10.1 & C8.11)

- The BM CC staff must be experienced in BM collection procedures and handling of HPC marrow products and well trained in the management of marrow donors (WMDA 8.03, JACIE CM3.3.1 & CM8.9)

- The staff must be sufficient in number to meet the needs of the CC's activities for daily and emergency coverage (WMDA 8.01, JACIE CM3.3.2 & C3.4.1)

General Requirements



Donor Health & Eligibility

Information Session & Informed Consent

Study Requests / Samples

Collection Procedure

Product Identification & Handover

Post Donation Care

Donor Health & Eligibility

- The medical assessment of the UD must be performed according to the national standards. WMDA Standards should also be applied at a minimum (WMDA8.01, JACIE CM1.3.1& C1.3.1)

- The risks of donation must be evaluated and documented, including: (WMDA 3.23, JACIE CM6.3.2& C6.3.2, C6.3.2.1-C6.3.2.3, B6.3.2.3 &6.3.4)

  - ✓ Possible need for central venous access
  - ✓ Mobilization therapy for collection of HPC and apheresis
  - ✓ Anesthesia and HPC BM collection
  - ✓ Pregnancy assessment for all female UDs according to national standards and regulations and WMDA Standards

Donor Health & Eligibility

- Infectious disease markers (IDMs) (WMDA 2014: 2.0) must be tested within 30 days prior to the HPC collection or according to the applicable law and national requirement as well as to WMDA Standards (WMDA 3.22.3 , 3.24-3.25, JACIE B6.4.9.1, C6.4.2 & C 6.4.2)

  - ✓ If country specific IDMs are required the UD must be tested for evidence of clinically relevant infection accordingly (WMDA3.24.1)

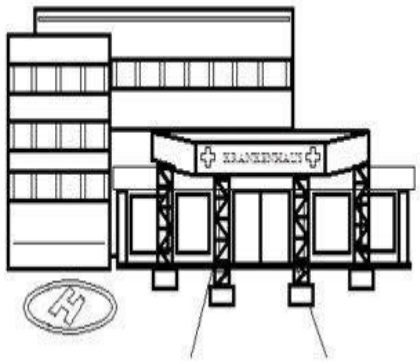
  - ✓ IDM testing must be carried out in a manner to ensure the safety and accuracy of the data (WMDA3.17.1)

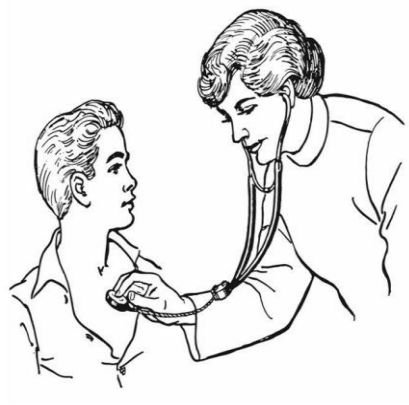
  - ✓ IDM testing must be carried out by laboratories that meet national requirements and standards (as well as international lab standards if applicable) (WMDA 3.17, JACIE C/CM 6.4.2)

  - ✓ Additional tests must be performed as required to assess the possibility of transmission of other infectious or non-infectious diseases (WMDA 3.23, JACIE B6.4.11)

  - ✓ UDs which have recently travelled outside their country should be evaluated for infectious agents prevalent in the areas of travel (WMDA 3.24.1, JACIE B6.4.6, 6.4.6.2 & 6.4.11)

General Requirements





Information Session & Informed Consent

Study Requests / Samples

Collection Procedure

Product Identification & Handover

Post Donation Care

Information Session & Informed Consent

- The information session with the UD must be performed according to WMDA Standards. National laws and regulations must be followed (WMDA 3.04, JACIE C/CM6.2.1..-6.2.1.4, 6.2.4, 6.2.5 & 6.2.5.1)

- The responsible physician or their designee must explain the procedure in a language and terms the donor can understand (WMDA3.04, 3.05, 3.06,3.11.1 & JACIE C/CM 6.2.1.1 – 6.2.1.4, C/CM 6.2.4, 6.2.5 & 6.2.5.1)

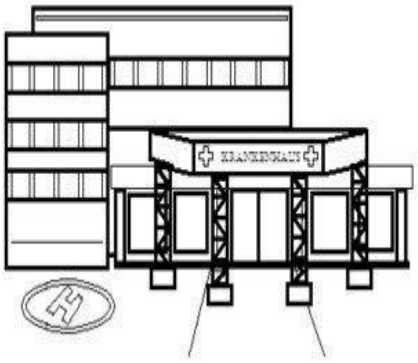
- The information session must cover the following topics at a minimum: (WMDA 3.10, 3.10.1, JACIE C/CM 6.2.1.1-6.2.1.4)

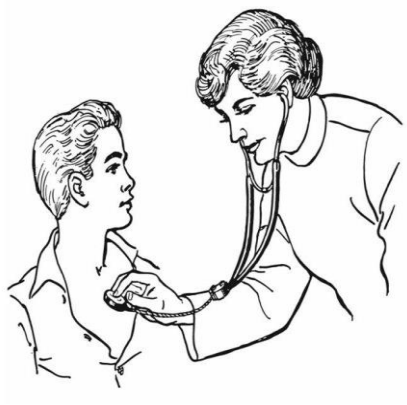
  - ✓ The risks and benefits of the procedure
  - ✓ The use of any medical intervention (e.g. administration of G-CSF), and its known risks and/ or side effects
  - ✓ Tests and procedures performed on the donor to protect the health of the recipient and the donor
  - ✓ Protection of medical information and confidentiality
  - ✓ The donor's right to refuse to donate

Information Session & Informed Consent

- According to WMDA Standards the UD must confirm his/her willingness to donate in writing (WMDA 3.03, JACIE CM6.2.6 and C6.2.6)
- The informed consent form must be written according to the national laws and regulations and must adhere to the WMDA Standards (WMDA3.11.1)
- The informed consent form must be written in a way that the UD is able to understand it before signing it (WMDA 3.11.1)
- The donor must have the opportunity to ask questions (WMDA 2.0, JACIE CM6.2.4 and C6.2.4)
- The donor must be informed about the (potential) consequences for the recipient, if he/she chooses to refuse to donate. This information may need to be in writing (follow your country requirements). He/she needs to know at which point during the process a refusal will have serious consequences (for example, refusal after the patient's conditioning has started) (WMDA 3.04, 3.10.1, JACIE C/CM6.2.5.1)

General Requirements





Study Requests / Samples

Collection Procedure

Product Identification & Handover

Post Donation Care

Study Request/Samples

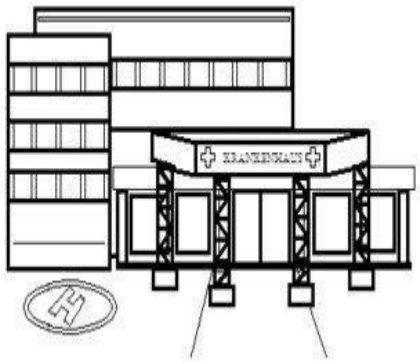
- In case the donor is considered a research subject, he/she must be informed about the research study appropriately according to WMDA Standards and recommendations as well as national laws and regulations (WMDA 3.10.1, 3.13, JACIE B8.3.2 & B 8.3.2.1-8.3.2.5)

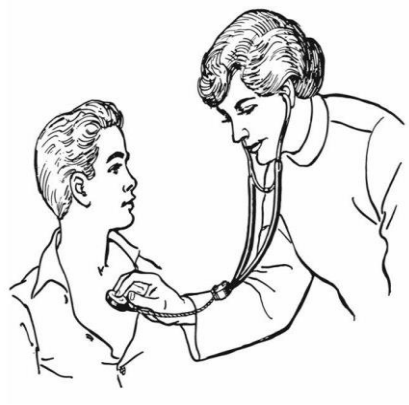
- The UD must sign a consent form , which will be provided by the study center. Some countries may have a requirements to have the study reviewed by the local institution (e.g. the ethical review board of the CC or registry) and/or adapt the consent form according to national laws (WMDA 8.13, JACIE B8.3.)

- The donor must have the opportunity to ask questions about the research study before signing the consent form (WMDA 2.0, JACIE B8.3.1)

- The donor must have the choice to decline participation in the research study. This needs to be clarified with the UD independently form the actual collection process (WMDA 3.10.1, JACIE B8.3.1)

General Requirements





Collection Procedure

Product Identification & Handover

Post Donation Care

Collection Procedure

- The collections must be performed according to national requirements and laws as well as WMDA Standards and recommendations. This includes G-CSF injection procedures for PBSC collections (WMDA8.01, 8.05, JACIE C/CM1.3.1)

- Administration of mobilization agents shall be performed according to WMDA Standards and/or national regulations and guidelines (WMDA 3.05,8.05,8.05.1,8.03, JACIE CM8.9 & C 8.11)

- There must be written documentation of the assessment of donor suitability for the collection procedure performed by a qualified person immediately prior to each collection procedure (WMDA3.19,3.02,8.03 2.05, JACIE CM8.7)

- If less than 2x10^6 CD34+ cells were collected, the need for further actions must be discussed. It is the responsibility of the CC physician to decide whether or not a 2nd apheresis or bone marrow collection is feasible and can be performed without affecting the health of the UD (WMDA5.05.1)

Collection Procedure

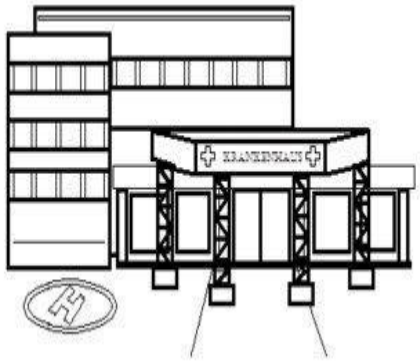
- The maximum harvested BM volume defined by the local authorities must not be exceeded (EDQM, 2015[ ]). The goal is to reach the optimal total nucleated cell (TNC) count in a relatively low volume of product.

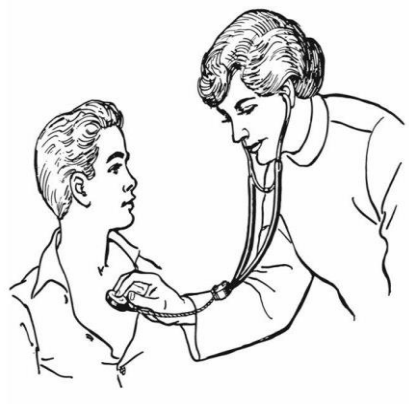
- General or regional anesthesia generally must be performed or supervised by a licensed, specialist-certified anesthesiologist. If this is not required by the national requirements, the registry-specific requirements must be followed (JACIE CM8.8)

- To comply with WMDA Standards and any national regulations, SEAR affecting donors undergoing collection of HPC and occurring either long term or short term as a consequence of the donation must be documented and investigated (WMDA8.09,8.10, 8.10.1, 8.10.2, 9.03, 9.03.1, 9.04 ,9.04.1, 9.04. JACIE C/CM4.10.3.1)

- Every S(P)EAR must be reported to the WMDA using the WMDA's international centralized database via the responsible registry or to the WMDA directly (WMDA 9.04)

General Requirements





Product Identification & Handover

Post Donation Care

Product Identification & Handover

- Each cellular therapy product must be labeled and coded according to national requirements and laws and applicable international regulations. The WMDA Standards for labeling should be taken into account (WMDA 8.07, JACIE CM7.3.1)

- The cellular therapy product, as well as samples from the UD and the product, must be labeled with the same UD identifier (WMDA 8.06, JACIE C/CM 7.3.1.1)

- If a single cellular collection product is stored in more than one bag, there must be a system to identify each container (JACIE C/CM7.3.1.2)

- To ensure that the product has been labeled with the correct label, labeling should be verified by two separate persons and verification of the labeling must be recorded (WMDA 8.06 ,8.07, JACIE C8.1, C/CM 7.3.1)

- The CC must have a process for assessing the quality of cellular therapy products to ensure their safety, viability, and integrity and to document that the product meets predetermined release specifications (WMDA 8.02, 8.06, 8.07, JACIE CM8.10, C8.12)

Product Identification & Handover

- The staff involved in the handover of the product must be appropriately trained in the handover procedure (WMDA 8.08)

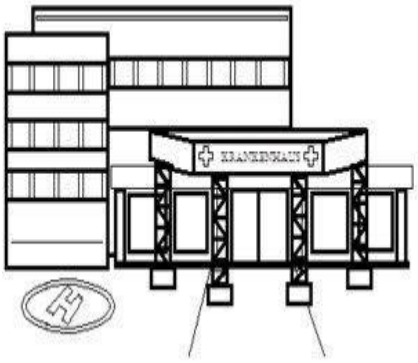
- The handover procedure must be performed according to WMDA recommendations and national requirements and cover at minimum the following steps: (WMDA Courier Guidelines 5.2)

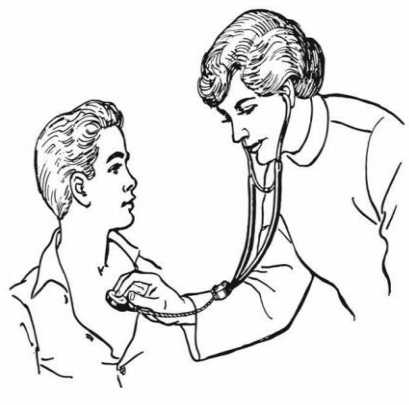
  - ✓ Ensuring the identity of the courier (WMDA 8.07,8.08, JACIE D11.3.6)

Product Identification & Handover

- Ensuring the proper preparation for transportation, checking at minimum the following:
  - ✓ The transportation paperwork and labeling is correct (WMDA 8.07)
  - ✓ The documentation is signed by two different people, e.g. cross-checking the information together with the courier (WMDA 8.08)
  - ✓ Any incident concerning the handover process (e.g. inadequate transportation equipment) needs to be reported to the responsible registry immediately (WMDA 8.08)
  - ✓ There must be a record of the date and time the cellular therapy product was handed over to the courier (WMDA 8.08, JACIE C/CM10.5)

General Requirements





Post Donation Care

Post Donation Care

- CC must provide the UD and registry with post-donation care instructions as required by the responsible UD registry (WMDA 9.01)

- The UD follow-up, in case this is the responsibility of the CC according to the agreements with the responsible registry, must be performed according to registry standards and any national regulations and laws (WMDA 9.01 & 9.02)

3. Specific Requirements (Soft Facts)

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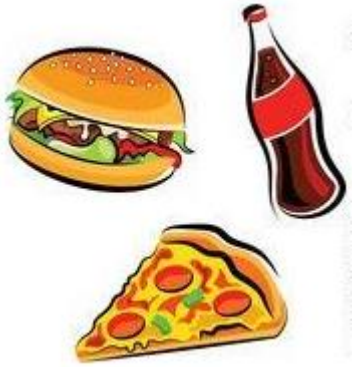
Soft Facts


VIP


Plan B
Plan C
Plan A
Plan D


AVAILABILITY




EFFICIENCY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3. Identification / Selection of a Collection Center with the example of DKMS Poland

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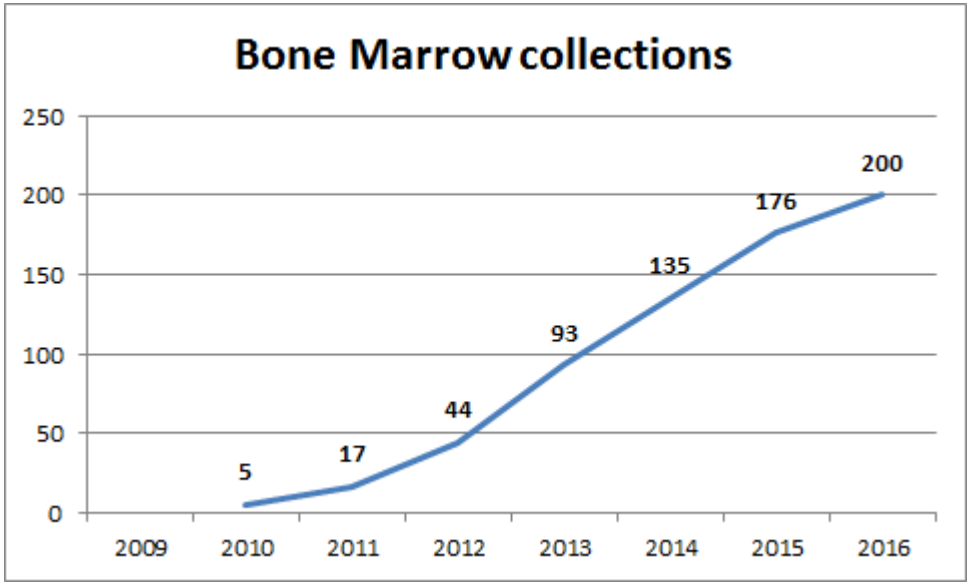
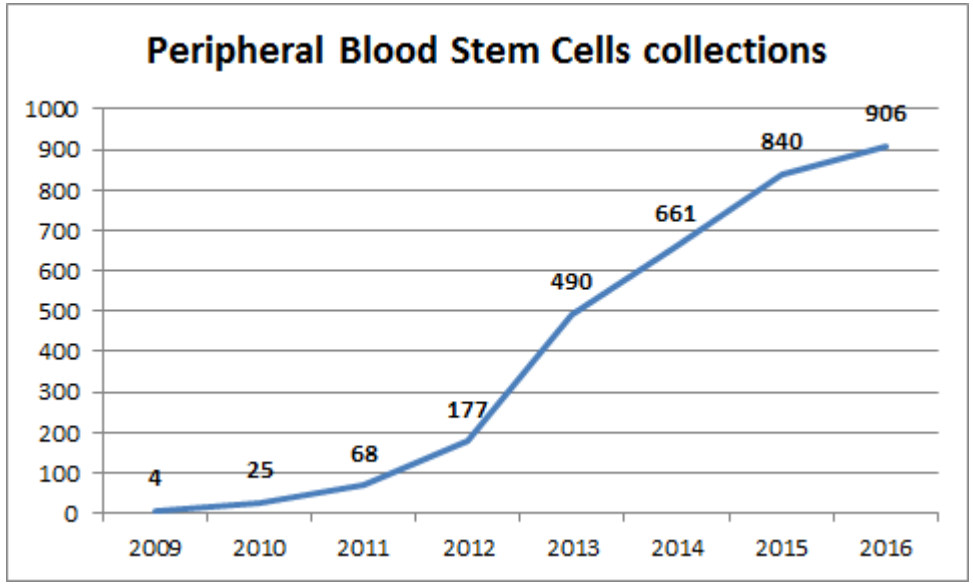
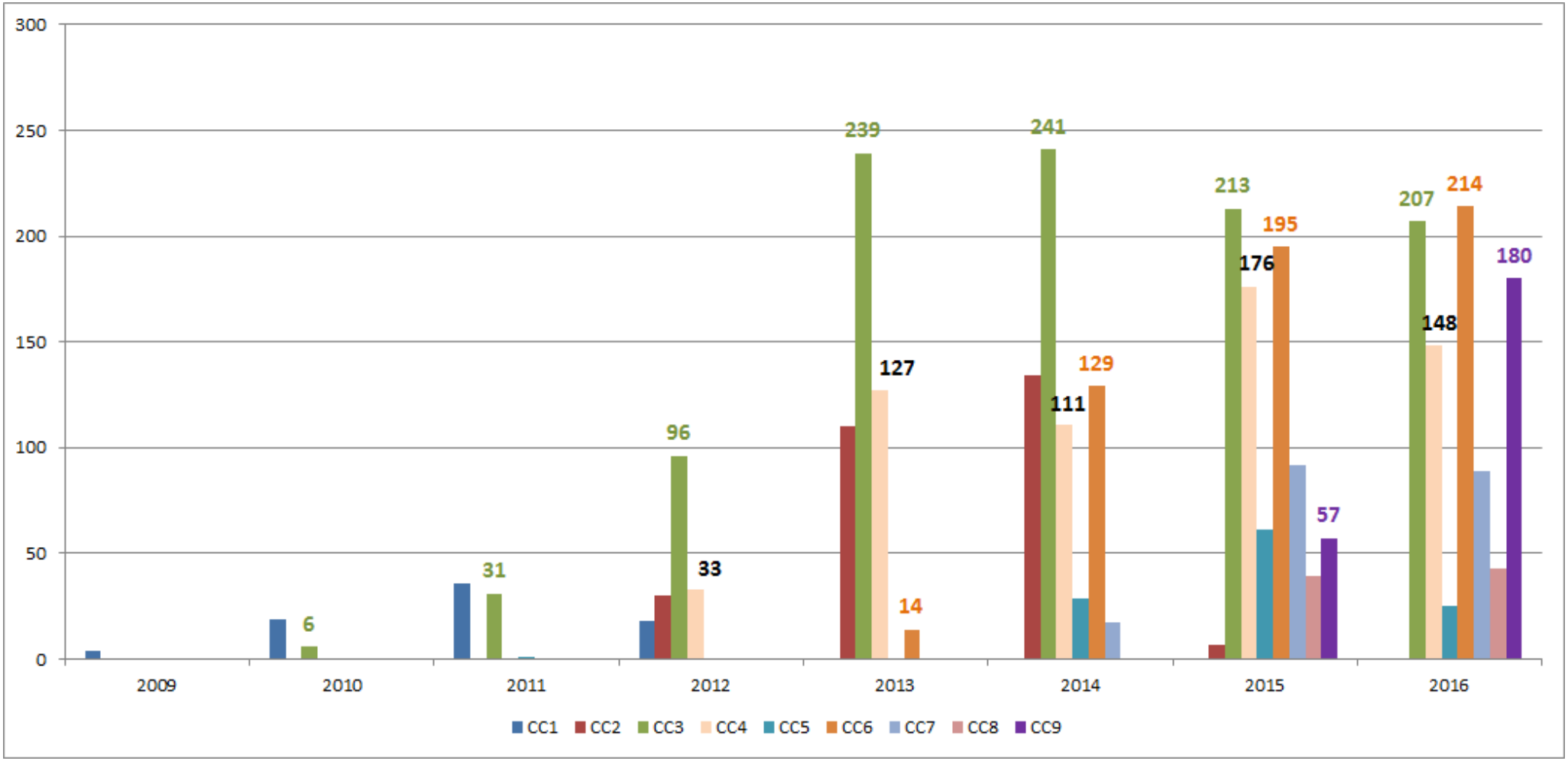
Increase in collections in DKMS Poland



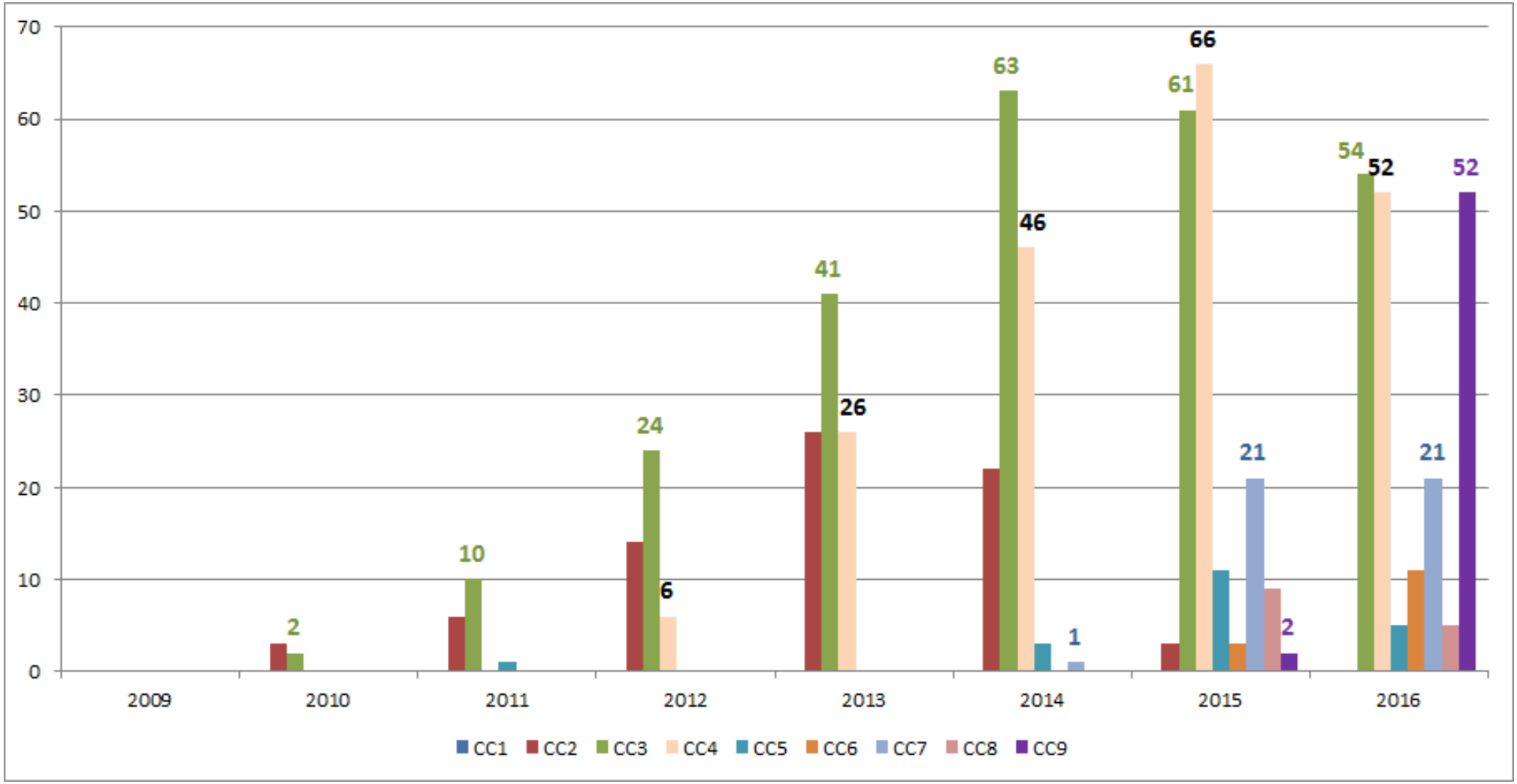


PBSC collections in Polish CCs



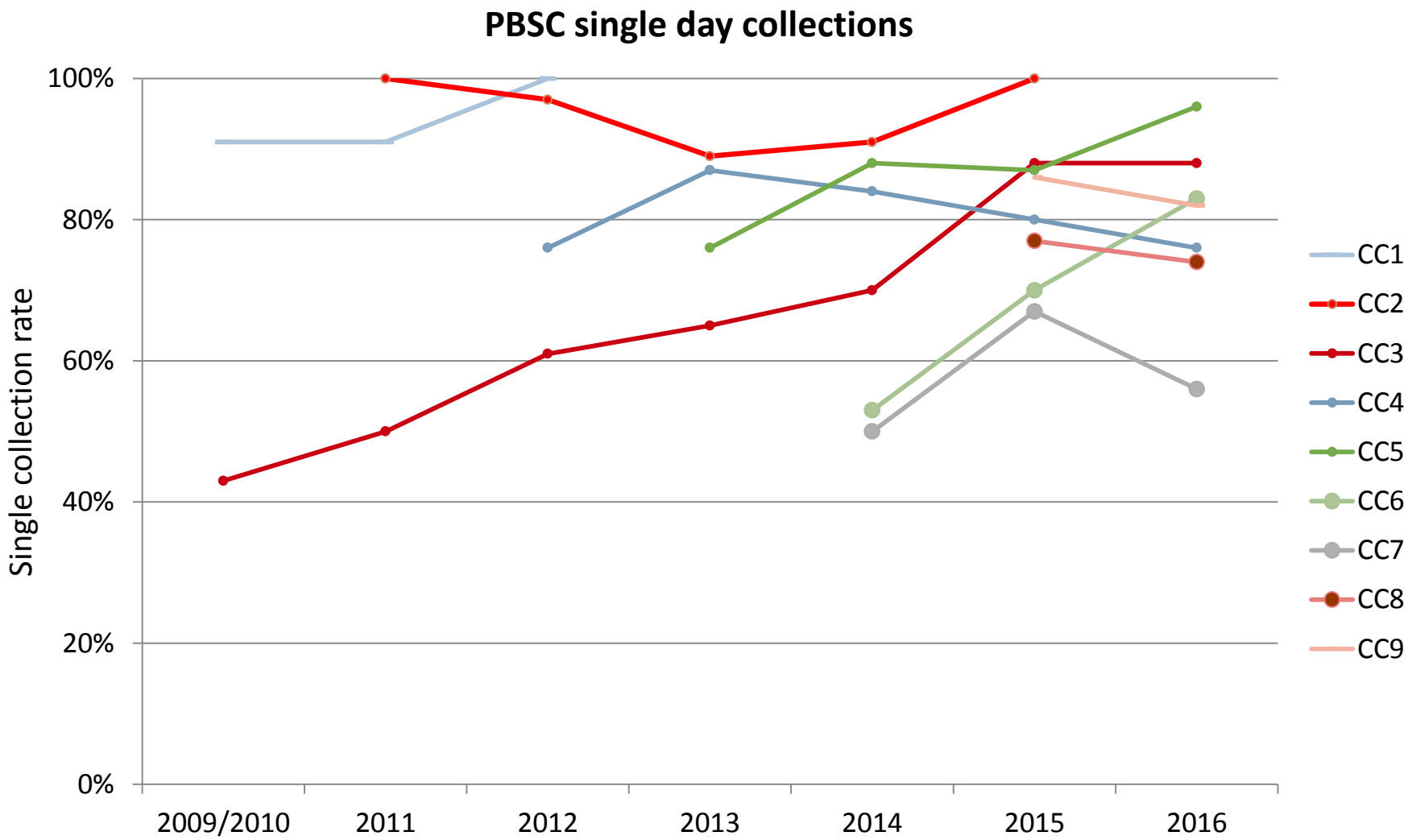
Average number of CD34+ cells collected from 1-day-apheresis in first quarter 2017 – 7,09x10^6 (vs. 6,75x10^6 in 2016)

BM collections in Polish CCs



Since 2015 our TNC concentration (1/nl) is stable and maintains the same level of 18,2/nl

PBSC single day collections



*Great majority of collections end after first day of collection with the CD34+ result not less than 4x10^6 cells/kg b.w.