

<u>Cell Collection and Management Manual</u> <u>Summary of changes - Updated to Version 4, October 2023</u>

- CARVYKTITM change to CARVYKTI®
- Overall grammar and spelling corrections
- Changed terminology: site to treatment center
- Page 2: added: "Central or Local cryopreservation. This will then ensure the proper shipper is sent to the treatment center"
- Page 2: separated central and local cryopreservation and clarified ordering option in treatment center portal
- Page 2: Contents: Cell Collection changed to page 5
- Page 2: for Local Cryopreservation, added: "with the treatment center or designated cell processing laboratory"
- Page 2: moved "apheresis collection bags should have 4 to 12 inches of tubing following collection to allow for future processing by welding onto this tubing" to page 5
- Page 3: updated definition of terms for CoC/CoI portal to "The Chain of Custody (CoC)/Chain of Identity (CoI) management portal is used to track the hand offs throughout the CARVYKTI® order fulfillment process"
- Page 5: under #3, added step 1 and 2: "In lieu of the treatment center's -specific procedures the guidance below can be utilized to achieve the target cell count for CARVYKTI® collections performed on the Spectra Optia®.
 - Step 1: Obtain patient WBC count within 24 hours prior to apheresis (cells/mL).
 - Step 2: Use the guidance below to estimate how many liters of whole blood to process. If patient's Pre-WBC count is > 12x 10e6, notify your Janssen Global Cell Collection
- Page 5: image added, as shown below

Patient Pre-WBC
<3x106 WBC/mL:
follow treatment
center SOP

Patient Pre-WBC 3-6x10⁶ WBC/mL: process up to 15 L Patient Pre-WBC >6x10⁶ WBC/mL: process up to 10 L

• Page 5: changed "mononuclear cell" to "white blood cell"