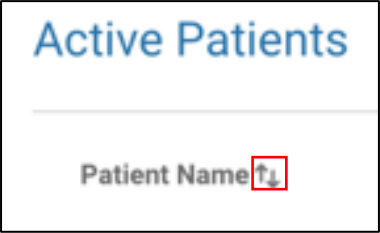| Kite — A GILEAD Company	**Memo**
Template: TMP-00582 v1.0	

APPROVED

To: Kite Konnect® Apheresis Collection Module (ACM) Users
From: Kite US Site Qualification (Quality) Team
Date: 09APR2023
Subject: Kite Konnect® Apheresis Collection Module (ACM) April 2023 Enhancements
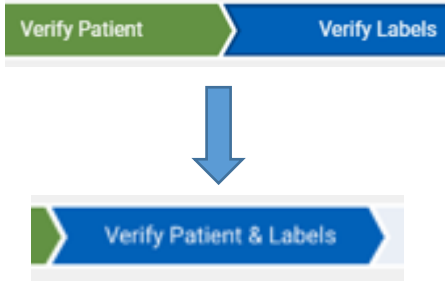
To Whom It May Concern:
Effective 15APR2023, Kite will upgrade its Kite Konnect® Apheresis Collection Module (ACM) with the following enhancements:

Enhancement	Examples and Rationale
1) Update to the 'sort' ability of the patient lists on the homepage. **Current State:** on the 'Active Patients', 'Completed Patients' and 'Cancelled Patients' tabs, users can only sort patients by Leukapheresis Date. **Future State:** users can now also sort by patient name by clicking the up and down arrows next to the 'Patient Name' column.	This allows users more options to find desired patients.
2) Addition of line item "**NanoCool**" to the list of "*Verification of the Apheresis Shipper Kit and Components*" at the "Verify Shipper" step of the ACM patient workflow. This item indicates the user should conduct a holistic inspection of the NanoCool shipper box itself for damage. Clicking the blue circled question mark brings up pictures of the NanoCool kit and instructs the user to check for damage.	Ensuring the kit and components are intact and ready for packing & shipping is currently being performed; inclusion of this line item ensures documentation of the holistic inspection.

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Date Printed	09 Apr 2023	Legacy Doc. No.	

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3)	The "Verify Patient" and "Verify Labels" chevrons in the ACM workflow have been merged into one step and will require only one set of digital signatures instead of two.	
		This reduces the number of steps and e-signatures users must now do for steps that are performed at the same time.
4)	When an ACM user clicks the "Initiate Multiple Bags" button on the Collection Checklist workflow step, a pop-up banner will appear stating "*Please contact your Kite Konnect Case Manager*" with the country appropriate Kite Konnect phone number.	As the use of the "Multiple Bag" collection process is rarely used, this pop-up is being added to remind users to contact Kite for support in ensuring all multiple bag collection ACM steps and processes are completed correctly.
5)	On the "Collection Checklist – Collection Summary" workflow step, users will now be able to use the "Edit Collection" button after the initial "Your Signature" has been populated. If any fields are edited in this manner, the "Your Signature" user will be required to re-enter their e-signature. Once the "Verifier Signature" is signed however, users will not be able to edit any fields.	This is being added so that if a Verifier sees a typo for correction post the "Your Signature" user has signed off, data corrections can still be made.

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6) The Temperature Monitoring Device Serial Number entered during the "*Verify Shipper*" ACM workflow step will now be present on the Apheresis Report.

Additionally, if the temperature monitoring device fails to activate during packing and shipping resulting in the user populating the "*Activate the Temperature Monitoring Device*" field on the Shipper Checklist as "No" they will be prompted to provide an issue reason and resolution action. When the new (backup) device is activated, the user will be required to populate the Temperature Monitoring Device Serial Number of the new device being utilized. The updated temperature monitoring device serial number will be the one present on the final Apheresis Report instead of the temperature monitoring device serial number entered on the "*Verify Shipper*" stage.

DOB (DD-MMM-YYYY)	15-Jul-1992	
Patient Weight	75 Kg	
Temperature Monitoring Device Serial Number	987654321	
Total Product Volume	2 mL	

This allows users to now have access to this information post collections via the apheresis report.

This memorandum is being provided for awareness of these upcoming changes. Note that the Kite provided user instructions (SOP-00309 Ver. No. 15 and WRK-05070 Ver. No. 8) have been updated accordingly and will be available in ACM for staff use no later than 17APR2023. Kite requests that you also update all institutional procedures and forms impacted by these enhancements (if applicable) in a timely manner. If you have any questions, please contact your Kite Quality representative.