

Research study monitor direct EMR access SOP*

Purpose: COVID-19 outbreak created the need for remote monitoring of research studies. The fast paced COVID environment, and shortage of staff within BMC and with 3rd party relationships, required the need for direct access into BMC's EMR for protocol required data confirmation through ChartLink. This decreases "over the shoulder" Zoom monitoring time for BMC staff and the sponsor. BMC will monitor this activity overtime to confirm the non-BMC staff and studies are removed from ChartLink when applicable and following expectations identified in signed agreements.

1. Clinical Trial Financial Analyst (CTFA) or BU equivalent determines if direct EMR monitoring will be needed for a study, if yes, then send Study Monitoring Memorandum of Agreement (MOA) to sponsor along with Clinical Trial Agreement (CTA)
2. MOA executed
3. Monitor(s) identified by the sponsor and sends names to study team and CTFA
4. CTFA sends each monitor Confidentiality Disclosure Agreement (CDA) to sign
5. CDA(s) executed and sent to CTFA and study team
6. Velos pre-award record complete, Epic upload triggered by CTFA, and Epic research IT creates Epic research record
7. CTFA submits REQ to create Chartlink Patient Group build for Research Study. Ticket should be submitted to group Emerge – AIR and should include what the Patient group should be called (ex. Novartis Research Study), and the study in Velos that it should be associated with:

The screenshot shows the BMC Service Management Suite interface for opening a request. The form includes fields for Name, Phone, Application, Building, Floor, Room, and ACO. The 'Short Description' field contains 'New Chartlink Group for Research Study'. The 'Detailed Description' field contains 'Please assign to Emerge-Air' and 'Requested Chartlink Group Name: RUXCOVID-DEVENT Research Study'. Two red arrows point from text boxes to the 'Requested Chartlink Group Name' and 'Research Study Name (In Velos): RUXCOVID-DEVENT' fields. The text boxes contain the instructions: 'Use the "Full Protocol Title" from Velos + "Research Study"' and 'Use the "Full Protocol Title" from Velos'. A 'Submit' button is visible at the bottom right.

- Let study team know once complete

8. CTFA submits REQ to create on boarding ticket for each monitor- The CDA should be attached to the ticket which includes; Full Name, Job Title, Employer(facility/research study name), email, and include Caitlin Gaudreau in the ticket. (Steps to be followed in Service Now are on the following page-4.)
9. IT team-Includes the helpdesk team and Emerge-Security. Helpdesk builds the BMC AD Name Emerge- Security builds the epic user name (which will be the same as AD name). IT team will wait until both tasks are done to let the user know as they won't be able to get into Chartlink until BOTH tasks have been created (and they do not happen at the same time). Creates user name and monitor will have to call for the password- 617-414-4500 (Service Desk number)
10. CRCs select which patients can be viewed in the study's ChartLink build
 - i. Consent documentation will be uploaded into the patient's EMR media section, through HIM, however this information cannot be viewed in ChartLink
 - ii. "Over the Shoulder" Zoom remote monitoring will be required to view the uploaded consent document(s)

11.



12. Monitor calls 617-414-4500 (Service Desk number) for the password

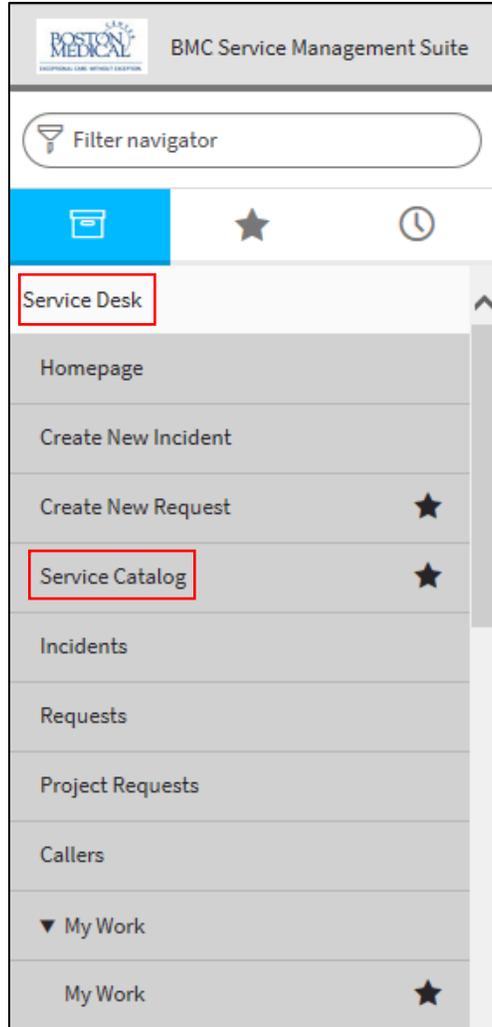
Contact the research coordinator for additional questions. If they are unable to resolve the issue then submit a REQ through Service Now assigned to eMergeAir.

*Note: this SOP does not include all required sign-offs and approvals necessary to have an active study at BMC, only the steps relevant to this SOP

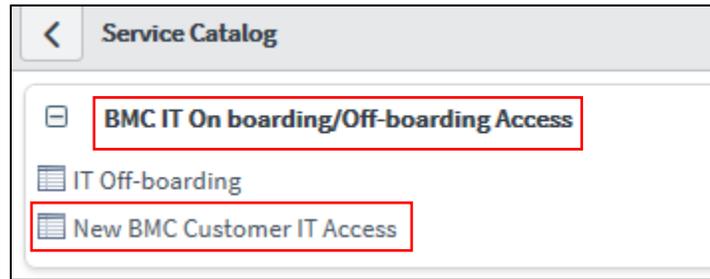
Application: Ambulatory
Release date: 5/1/2020

 Requesting Chartlink Access for Research Monitor Users in Service Now

1. Open Service Now
2. On the left hand side, Click on "Service Desk" and then "Service Catalog"



- Once in the Service Catalog, expand "BMC On boarding/Off-boarding Access"



- Then Select "New BMC Customer IT Access"
- In the form that pops up, first fill out the "Profile Type" field with "CHC – Community Health Centers (Chartlink)"
- Define "CHC Organization" next. (Usually this is the organization you are requesting access for but chances are that the *Research Study* will not be there. Define **Episource**, as this field is Mandatory)
- Once these fields have been defined, enter "Full Name" (Customer getting access) and "Manager" (define Kuang Lai – manager of Chartlink team) and "Title" fields (this field you may have to go back and enter) as I believe it appears later.

- Under "Account Access Type" please put **Other**,

9. "Comments" box type "Chartlink access needed for [Research Study Name]. Please associate this user to user context of [Research Study Name]. NDA is located on page #." Please cite the research study name that was used to create the Chartlink Group (ie. Novartis) (If the NDA is part of a document that includes several NDA's in one document include page number, otherwise omit from comments)

* Account Access Type
Other

Application Access

- DoseEdge
- eMerge/Epic Account
- Pyxis ES
- eReferral
- Sunquest
- EWS
- Jiva
- Arcadia
- THRIVE
- Logiclam
- M, Modal
- OR Scheduler
- PACS
- Patient Keeper
- SDK
- Remote Access
- Other
- Select All

Order New Hardware

- Office Phone
- Pager
- Cell Phone

Comments

Chartlink Access

10. Scroll to the very top of the page and hit the paperclip in the top right corner to attach the NDA.
11. Once the NDA is attached hit Submit, then Save and Exit.

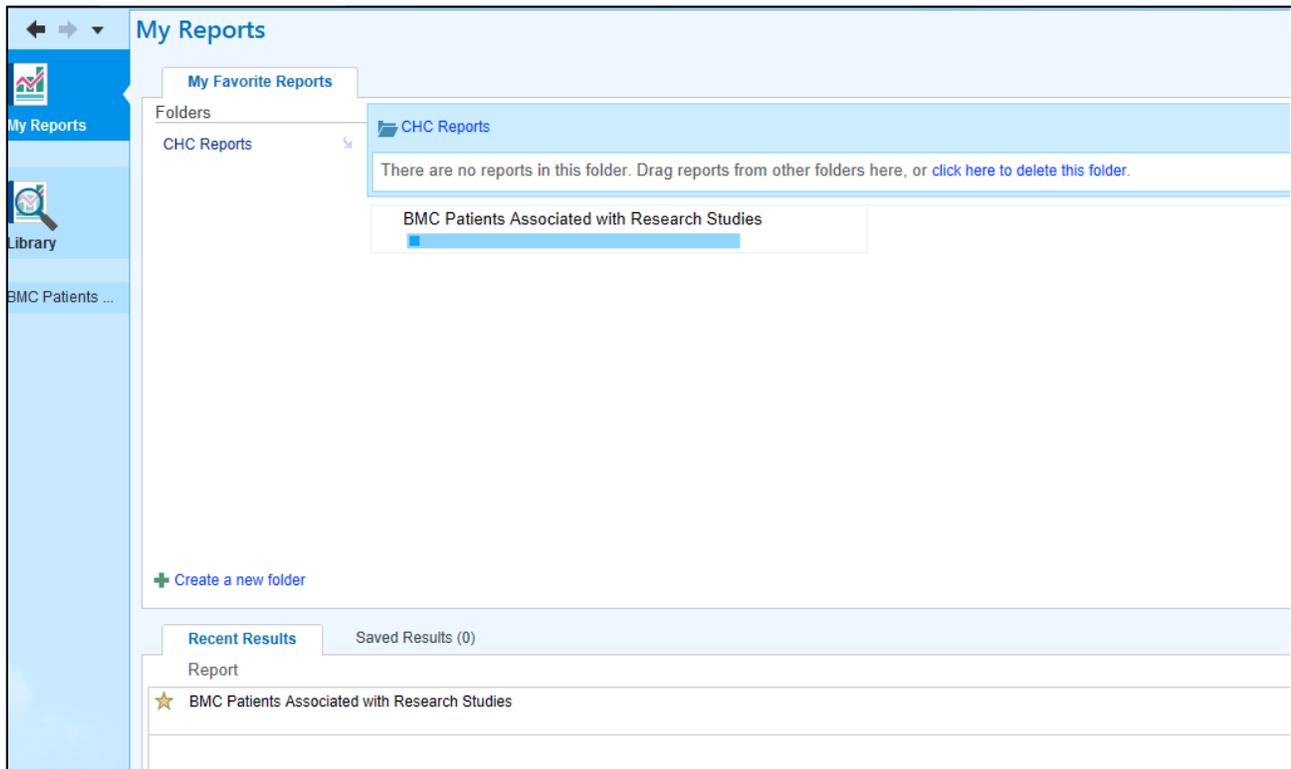
Application: Ambulatory
Release date: 4/1/2020

Research Coordinator add Patient to Chartlink

Research Coordinator: How to add patients to Research Group so that Study Monitor can see them in Chartlink

(Please make sure that all the all coordinators who would be adding patients to chartlink groups for research studies will need the **BMC RSCH AUDITOR SUBTEMPLATE [T00685] sub template added to their user profile**. Without which the study coordinator might not be able to view BMC Patients Associated with the Research Studies Report.)

1. Open Hyperspace and go to My Reports.
2. Run the “BMC Patients Associated with Research Studies Report” which you have starred.



- Once the report compiles you will see a list of patients in a research study. You will use this report to add patients to Chartlink for the Study Monitors

BMC Find Patients Associated with Research Studies [16909] as of Thu 4/30/2020 10:21 AM

Filters Options Re-run Report Research Studies Chart Encounter Add to List Communication Release to Study Monitor

Patient	DOB	Sex	MRN	Has Mult?	Participant ID	Study Code	Study Name	Enrollment Status
Research, Chandler	01/01/1977	Male	9211042	No		H-35295	Smoking Cessation	Enrolled
Research, Monica	01/01/1977	Female	9211039	No		H-35295	Smoking Cessation	Enrolled
Research, Phoebe	01/01/1978	Female	9211043	No		H-35295	Smoking Cessation	Enrolled
Test, Bridges Edi	01/01/1989	Female	9200290	No	Vct-0000644	2323235645f	interfaceuser_velosqa_oct26test Test RPE 10012019 ...	Consented
Test, Yawpedigispch	08/14/2009	Female	9210521	No		H-35899	Actis Total Hip System	Enrolled

- Highlight the patient that you want to add to Chartlink and hit the "Release to Study Monitor" button.



- In the box that pops up, you fill out the Research Study name, Chartlink Patient Group, and period of time that you want to release the patient for. When filling out the to/from dates, you can use T for today and +days to calculate the date automatically.

Release to Study Monitor

Research Study: Smoking Cessation

Patient Group: Novartis Research Study

Release From Date: 4/30/2020

Release To Date: 5/7/2020

Release Cancel

- When finished press the release button and the patient will be added to the group listed above.

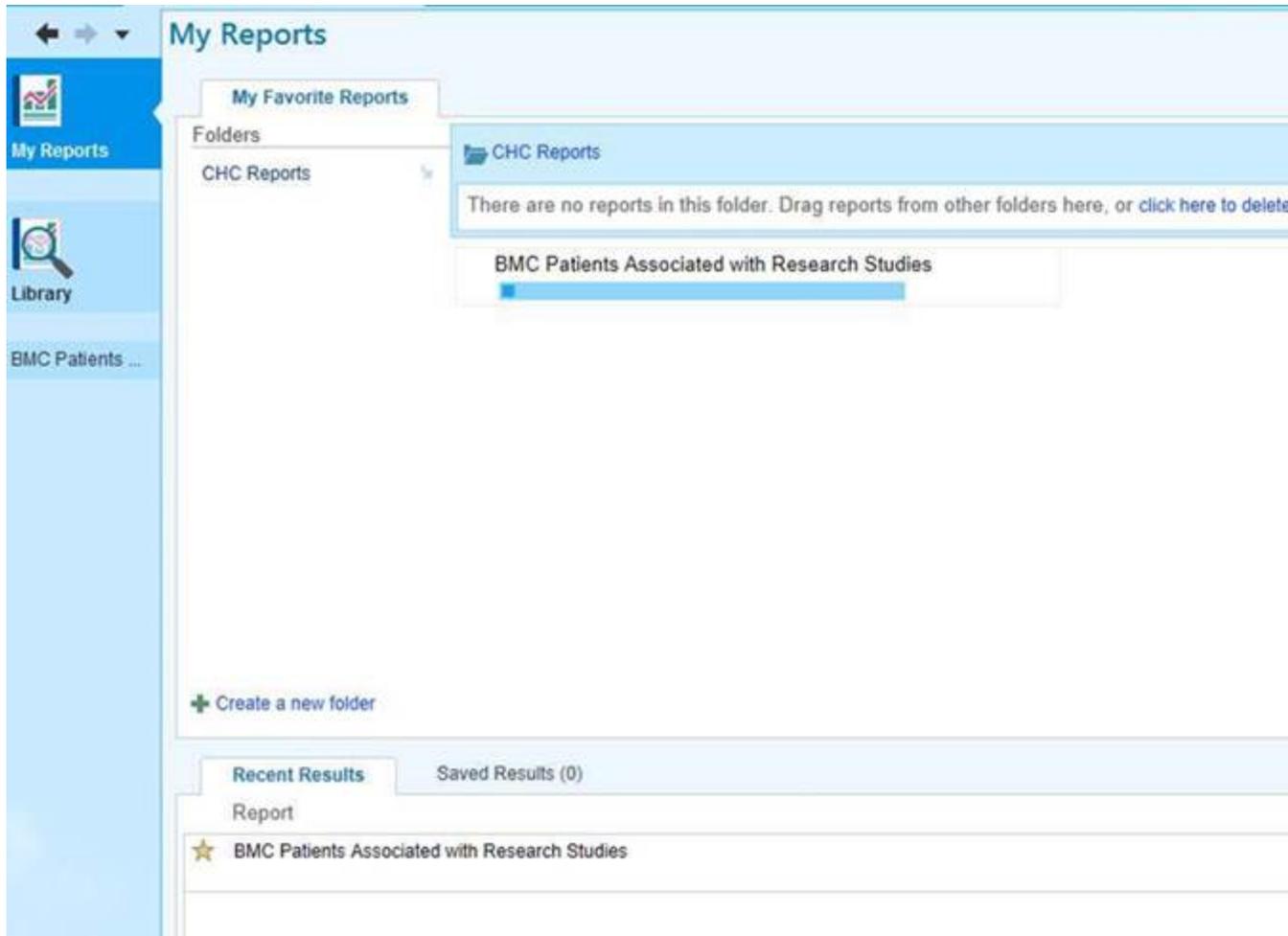
To access the BMC patients associated with research studies report please follow these steps:

1. In Epic go to Reports on your toolbar and choose My reports.
2. We are going to add this report to your My report section....but first you need to find it in the Library
3. Go to the Library and in the search put "Research".
4. You will want to star the report circled here:

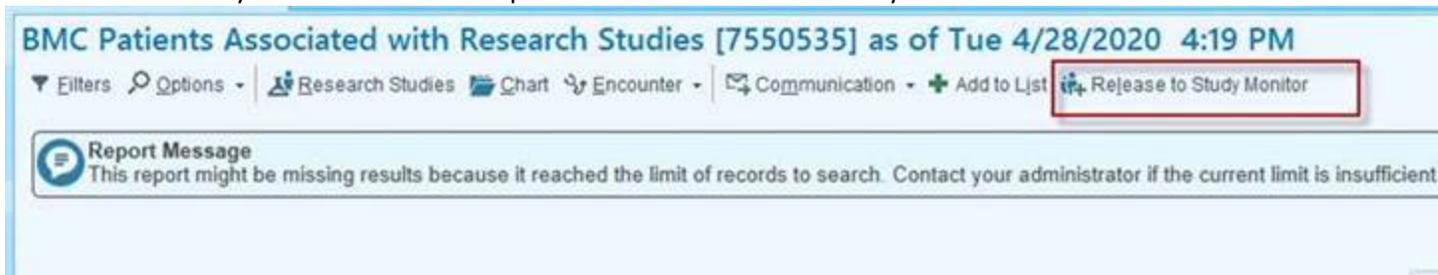
The screenshot shows the Epic Reports Library interface. At the top, there is a search bar with the text 'research' and buttons for 'Search' and 'Clear'. Below the search bar, several report categories are listed, each with a 'Matching reports' section. The reports are:

- BMC Development Research Monthly Patient Report (Crystal)**
 - ☆ BMC Development Research Monthly Patient Report Crystal
- BMC Development Research Monthly Patient Report Unique Visits (Crystal)**
 - ☆ BMC Development Research Monthly Rerport Unique Visits (Crystal) Crystal
- BMC ES Appt Search For Research Coordinators**
- BMC Find Patients Associated with My Research Studies**
 - ☆ BMC Patients Associated with Research Studies
This report shows patients enrolled on all research studies.
- BMC HB Transaction Query**
 - ☆ BMC HB Research Transactions - Misc
 - ☆ BMC Research Transactions - Last Month Charges
- BMC Patients Needing Research Billing Review**
 - ☆ BMC Patients Needing Research Billing Review (Biller)
- BMC PB Aged AR**
 - ☆ BMC PB Aged Research AR
Looks at AR associated with research guarantor accounts
- BMC PB Generic Outstanding Transaction Search**
 - ☆ BMC PB Outstanding Research Charges
Shows outstanding charges in research AR/associated with research guarantor accounts
- ES Appt Search For Research Coordinators**

5. Once this report is starred you will be able to see it in your My Reports section as can be seen here:



6. When you run this report you should see the toolbar item "Release to Study Monitor" (this is the button you will use to add the patient to Chartlink for the Study monitor:



Please, contact Margie Canady if you have any issues getting this report or if you don't see the Release To Study Monitor Button.

Self Guided Training within the Chartlink Application

The screenshot displays the BMC ChartLink application interface. At the top, there is a navigation bar with the Epic logo, Home, In Basket (with a 59+ notification), Patient List, and Patient icons. On the right side of the navigation bar are Menu and Log Out options. Below the navigation bar, a welcome message reads "Welcome to BMC ChartLink, powered by Epic." To the right of this message are window control icons and a help icon. The main content area features the Boston Medical Center logo and the text "Chartlink". Below the logo are three action buttons: "Select Patient" (with a magnifying glass icon), "Open Chart Review" (with a folder and checkmark icon), and "View In Basket" (with a clipboard icon). On the left side, there is a section titled "Unread Messages" with a list of message categories and counts: Appointment Requests (130), MyChart Advice (941), MyChart Rx Request (1393), Patient Clinical Update (817), Patient Questionnaires (693), Pt Activation Code Request (43), Pt Non-Clinical Update (59), Pt Records Request (11), Rx Request (235) with a red upward arrow, and Rx Response (2). On the right side, there is a "Quick Links" section with a star icon and a list of links: How to Get Started, ChartLink Basics, Training Video, and FAQs. At the bottom left, it says "Logged in as: GREANEY, MARGIE". At the bottom right, it says "EpicCare® Link and Tapestry® Link licensed from Epic Systems Corporation, © 1979-2020 Epic Systems Corporation."