

# PowerTrials: Prescreening Function

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**Bear Institute**

Part of the Children's National Health System



A PARTNERSHIP WITH THE GEORGE WASHINGTON UNIVERSITY

# Overview - PowerTrials

- A Cerner application consisting of three primary functions:

## 1) Participant Enrollment Function

- EMR-based entry/tracking of patient enrollment data & study information

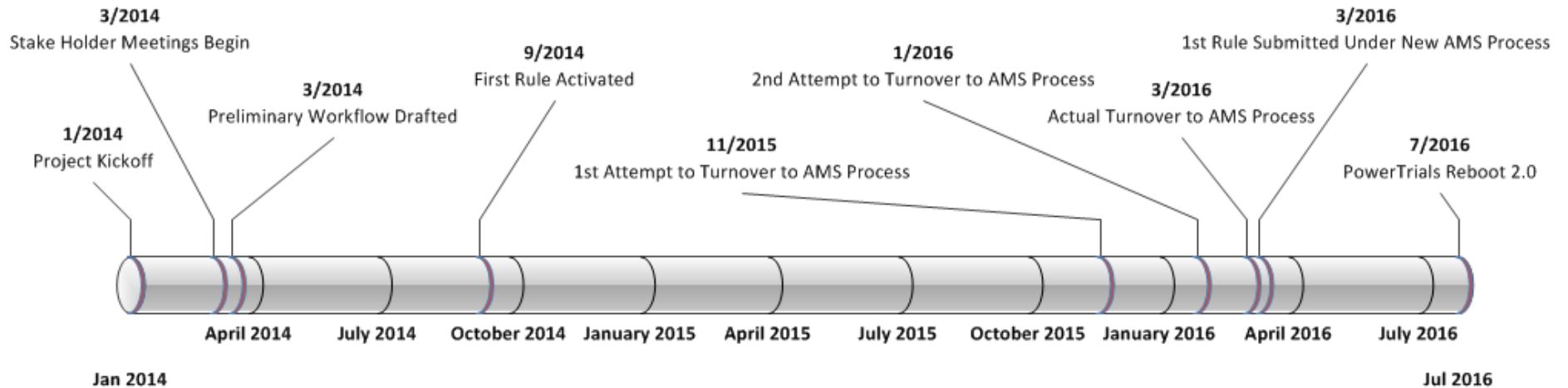
## 2) Revenue Cycle Management

- Track and manage research patient billing/reimbursement

## 3) Prescreening Function

- EMR-based prescreening of potential study patients

# Overview – PowerTrials Project Timeline





# General Overview – Prescreening Function

- **HIPAA complaint application (uses same standards as the EMR)**
- **Enables investigators to search for research participants within the EMR**
  - Based on pre-established, IRB approved inclusion/exclusion criteria
- **Access limited strictly to Children's National investigators, study nurses/coordinators, etc.**

# Process Overview – Prescreening Function



\*The above may occur concurrently

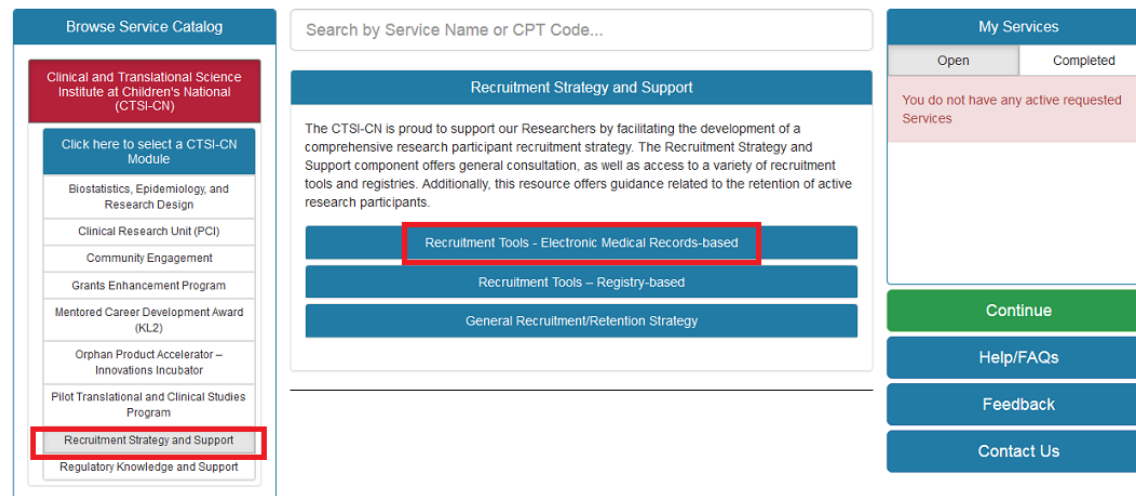
# Process Overview – Consultation

- [www.ctsicc.org](http://www.ctsicc.org) → SPARC Request
- Create account – Necessary to request most CTSI-CN resources
- Select “Recruitment Strategy and Support” to request a consultation



## STEP 1: Add/Update Services

### About SPARCRequest



The screenshot shows the 'Recruitment Strategy and Support' page. On the left is a 'Browse Service Catalog' sidebar with a red box around 'Recruitment Strategy and Support'. The main content area has a search bar and a description of the service. Below the description are three buttons: 'Recruitment Tools - Electronic Medical Records-based' (highlighted with a red box), 'Recruitment Tools – Registry-based', and 'General Recruitment/Retention Strategy'. On the right is a 'My Services' panel showing 'Open' and 'Completed' tabs, with a message 'You do not have any active requested Services' and buttons for 'Continue', 'Help/FAQs', 'Feedback', and 'Contact Us'.

# Process Overview – Feasibility

- **Initial assessment of criteria by PowerTrials Support Team**
  - Types of criteria (e.g., lab values, ICD-10 codes, procedure codes, patient location)
  - Type of study - **PROSPECTIVE ONLY**
- **In-depth Feasibility Assessment**
  - Communication between Cerner's Development Team and the PowerTrials Support Team
    - Further assess Prescreening Rule criteria
    - Narrow/Broaden search criteria
    - Preliminary review of criteria feasibility
    - Q/A

# Process Overview – Training



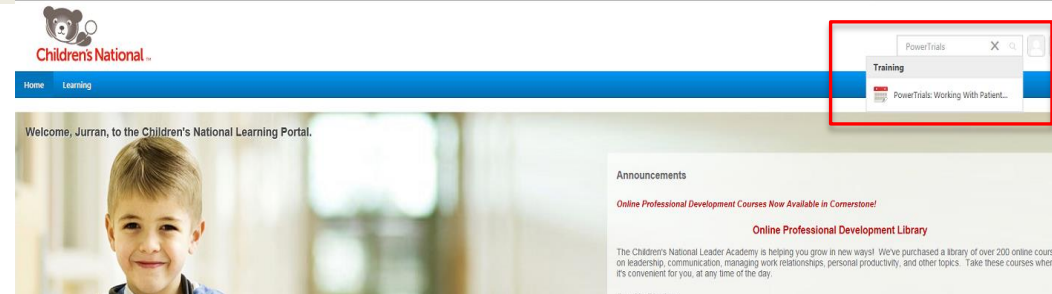
- **Cornerstone learning portal**
  - Accessible via Children's National Intranet
  - Search "PowerTrials" for course registration

- **In-person training course**

- Approximately 45 mins. – Scheduled to suit study team
- Learn how to:
  - Access and navigate the Patient Protocol Manager (PPM) application
  - Prescreen patients located in PowerChart (EMR) for potential recruitment
  - Enroll patients to your specific protocol

- **Brief exam located in Cornerstone**

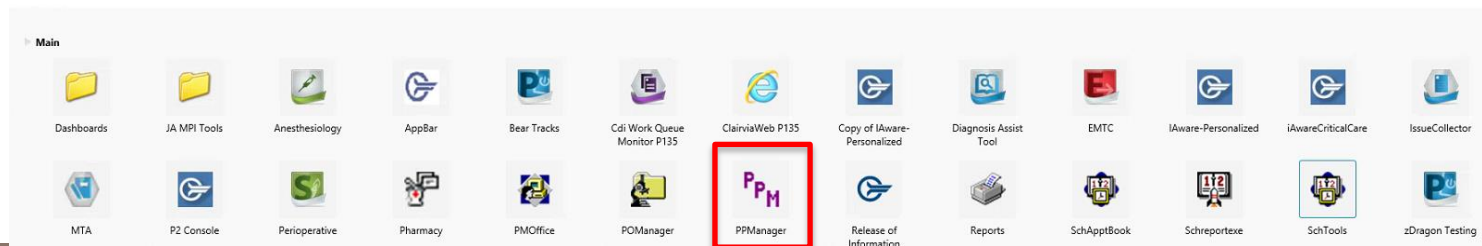
- At least 80% correct answers to pass





# Process Overview – Access

- **All study staff require training to use PowerTrials**
  - Included investigators, study nurses, study coordinators, etc.
- **PPM application**
  - Accessed via Intranet/Citrix Receiver (same as EMR)
  - Current PowerChart access is required to obtain PPM access
  - Once training/exam completed:
    - Clinicians – PPM application automatically loaded in CernerWorks
    - Research Nurses - require Help Desk request/CNID\*
    - Research Coordinators/Other - Help Desk request/ CNID\*



\*Only if no current access to PowerChart

# Process Overview – IRB Process

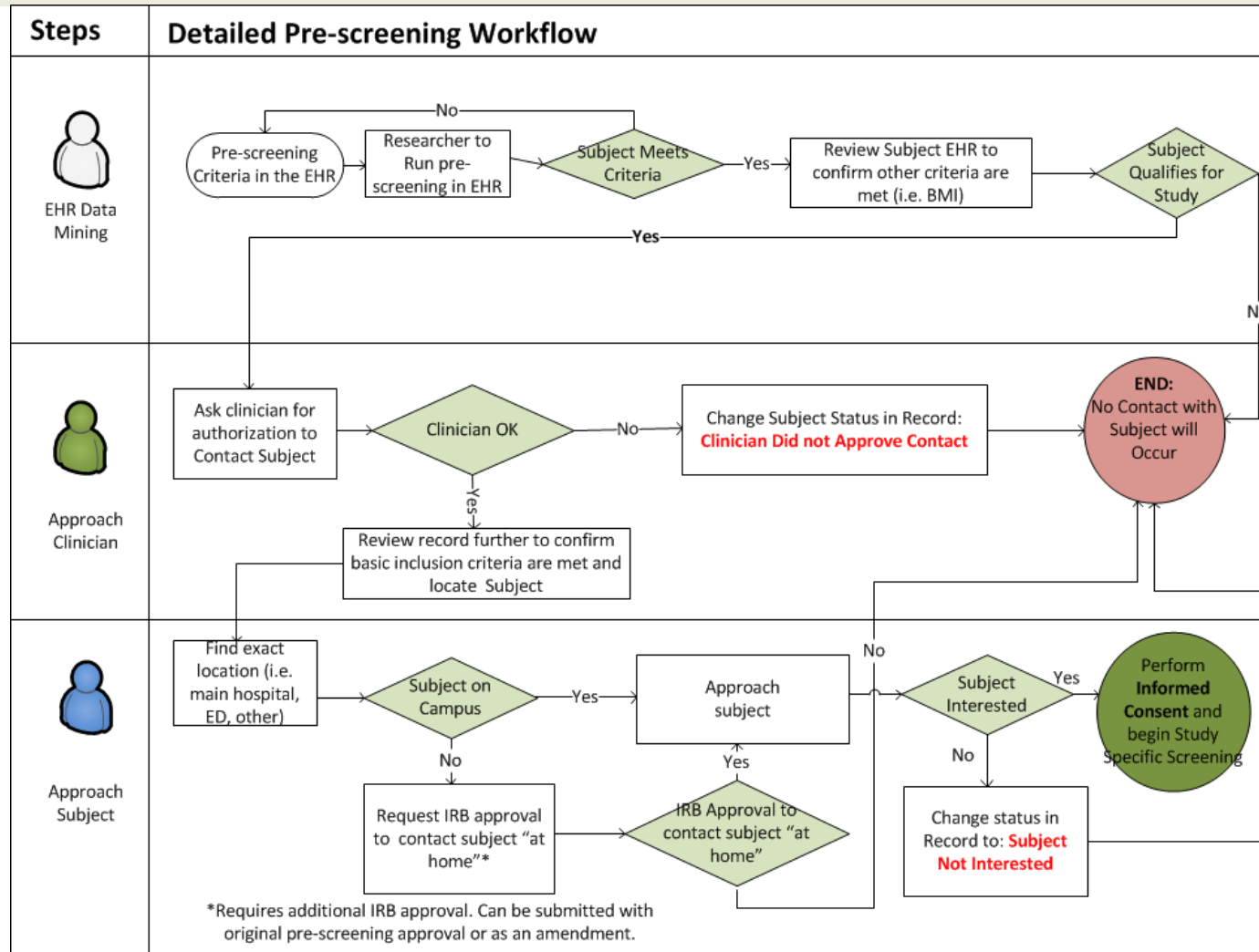
- **Only studies that have received general IRB approval and have been approved by the IRB to use PowerTrials Prescreening will be allowed to utilize a Prescreening rule**
  - Copy of IRB approval letter must be submitted to PowerTrials Support Team
- **IRB of Record**
  - Children’s National IRB (IRBear)
  - Western IRB (WIRB Connexus) \*
  - External Central IRB (i.e., Review from a different institution/non-affiliated IRB) \*



# Process Overview – IRB Approval

- **IRB Approval Process**
  - **Children's National IRB and WIRB – An established process has been developed for the approval of PowerTrials Prescreening as a recruitment method**
    - New Study vs. Study Amendment
    - PowerTrials Prescreening Function Procedure documents on [CTSI-CN](#) website
    - *Note: Requires ancillary review (PR and Marketing and Medical Records)*
  - **External Central IRB**
    - New Study – Requires Facilitated Review submission within IRBear + any additional approval requirements required by external/central IRB
    - Study Amendment – Requires submission of amendment to IRBear (use established procedure) + any additional approval requirements by external/central IRB

# Process Overview – Prescreening Workflow



# Process Overview – Begin Prescreening

- Once all previous steps have been completed:
  - **PowerTrials Support Team and Study Team will test the Prescreening Rule**
    - “Dummy Data” → Actual Children’s National patients
    - Prescreening function will be fully activated

PowerTrials: Patient Protocol Manager - 30600 Ctr for Clinical & Community Resea - LALD

Task View Help

Enrollment

Pre-Screened Patients

Consents Pending Sig...

All Patients Enrolled

To Be Verified

Still On Study

All Pre-Screened Patients Patient Count: 56

Filter by the following status: All

Last Name	First Name	MRN	Protocol Name	Pre-Screened Status	Pre-Screened By	Pre-S
LALD	Pending	Wilson, Jurrant	CRC II 02/2			
LALD	Pending	Wilson, Jurrant	CRC II 03/3			
LALD	Pending	Wilson, Jurrant	CRC II 10/1			
LALD	Pending	Wilson, Jurrant	CRC II 09/0			
LALD	Pending	Wilson, Jurrant	CRC II 03/0			
LALD	Pending	Wilson, Jurrant	CRC II 03/3			
LALD	Pending	Wilson, Jurrant	CRC II 01/1			
LALD	Pending	Wilson, Jurrant	LHC II U3/3			
LALD	Pending	Wilson, Jurrant	CRC II 09/1			
LALD	Pending	Wilson, Jurrant	CRC II 03/0			
LALD	Pending	Wilson, Jurrant	CRC II 02/0			
LALD	Pending	Wilson, Jurrant	CRC II 12/2			
LALD	Pending	Wilson, Jurrant	CRC II 09/0			
LALD	Pending	Wilson, Jurrant	LHC II 11/2			
LALD	Pending	Wilson, Jurrant	CRC II 03/2			
LALD	Pending	Wilson, Jurrant	CRC II 02/2			
LALD	Pending	Wilson, Jurrant	CRC II 03/3			
LALD	Pending	Wilson, Jurrant	CRC II 11/2			
LALD	Pending	Wilson, Jurrant	CRC II 03/3			
LALD	Pending	Wilson, Jurrant	CRC II 03/3			
LALD	Pending	Wilson, Jurrant	CRC II 09/0			
LALD	Pending	Wilson, Jurrant	CRC II 12/2			
LALD	Pending	Wilson, Jurrant	CRC II 03/0			
LALD	Pending	Wilson, Jurrant	CRC II 01/1			
LALD	Pending	Wilson, Jurrant	CRC II 12/2			
LALD	Pending	Wilson, Jurrant	CRC II 03/2			
LALD	Pending	Wilson, Jurrant	CRC II 09/1			
LALD	Pending	Wilson, Jurrant	CRC II 03/3			
LALD	Pending	Wilson, Jurrant	CRC II 03/3			
LALD	Pending	Wilson, Jurrant	CRC II 12/2			
LALD	Pending	Wilson, Jurrant	CRC II 12/2			
LALD	Pending	Wilson, Jurrant	CRC II 02/0			
LALD	Pending	Wilson, Jurrant	CRC II 12/2			
LALD	Pending	Wilson, Jurrant	CRC II 03/0			



# Process Overview – Optimization (If necessary)

- **In-depth review of Prescreening Rule functionality**
  - **Meeting with Cerner Development Team, PowerTrials Support Team, and Study Team**
    - Assess accuracy of Prescreening Rule
    - Modifications (as needed; must fall within IRB approved criteria)
    - Quality Assurance
  - **Ongoing technical and regulatory support available**

# PowerTrials - Questions



All general/technical questions regarding PowerTrials Prescreening may be directed to Jurrán Wilson ([juwilson@childrensnational.org](mailto:juwilson@childrensnational.org); 202.476.2196)



*Wishing you great success with your enrollment and recruitment efforts,  
The Children's National PowerTrials Team*