PowerTrials: Prescreening Function

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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

- **3/2014**: Stake Holder Meetings Begin
- **1/2014**: Project Kickoff
- **3/2014**: Preliminary Workflow Drafted
- **9/2014**: First Rule Activated
- **1/2016**: 1st Attempt to Turnover to AMS Process
- **11/2015**: 2nd Attempt to Turnover to AMS Process
- **3/2016**: Actual Turnover to AMS Process
- **3/2016**: 1st Rule Submitted Under New AMS Process
- **7/2016**: PowerTrials Reboot 2.0

Timeline:
- April 2014
- July 2014
- October 2014
- January 2015
- April 2015
- July 2015
- October 2015
- January 2016
- April 2016
- July 2016
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

- Consultation
- Feasibility
- IRB Approval Process
- Begin Prescreening
- Optimization
- Training/Access
- Rule Development
- Rule Testing/Activation

*The above may occur concurrently

KEY
- ST: Study Team
- RA: Research Administrator
- C: Cerner

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Process Overview – Consultation

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

*Require facilitated review by Children’s National 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

Steps | Detailed Pre-screening Workflow
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### EHR Data Mining
- Pre-screening Criteria in the EHR
- Researcher to Run pre-screening in EHR
  - Subject Meets Criteria
    - Yes: Review Subject EHR to confirm other criteria are met (i.e. BMI)
    - No: Subject Qualifies for Study

### Approach Clinician
- Ask clinician for authorization to Contact Subject
  - Clinician OK
    - Yes: Change Subject Status in Record: Clinician Did not Approve Contact
    - No: END: No Contact with Subject will Occur
  - Review record further to confirm basic inclusion criteria are met and locate Subject

### Approach Subject
- Find exact location (i.e. main hospital, ED, other)
- Subject on Campus
  - Yes: Approach subject
  - No: Request IRB approval to contact subject "at home"
- IRB Approval to contact subject "at home"
  - Yes: Approach subject
  - No: Subject Interested
- Subject Interested
  - Yes: Perform Informed Consent and begin Study Specific Screening
  - No: Change status in Record to: Subject Not Interested

*Requires additional IRB approval. Can be submitted with original pre-screening approval or as an amendment.*
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
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
All general/technical questions regarding PowerTrials Prescreening may be directed to Jurran Wilson (juwilson@childrensnational.org; 202.476.2196)

Wishing you great success with your enrollment and recruitment efforts,

The Children’s National PowerTrials Team