Building ADRC Recruitment and Research Data Management Tools: Lessons Learned in Wisconsin

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Inspiring Hope for the Future
Presentation Overview

- Starting point
- Using a Systems approach
  - Defining data needs and processes
  - Identifying opportunities
  - Process planning
- Achieving results
Wisconsin ADRC Data Management

A Systems view of Data Management

- Data management as a process within the ADRC
- Multiple data management processes
- Data needs within and across all processes
Wisconsin ADRC Data Management Needs

Clinical Core Subjects

- AD / MCI diagnosed
- Healthy Older Adult Controls
- Middle-aged at-risk Adults (parental history positive/negative)
Wisconsin ADRC Data Management Needs

Current/past Wisconsin Comprehensive Memory Program (WCMP) participants
- 2,000+ in database

Outreach and recruitment to underserved / underrepresented populations
- Low-income
- Minorities
- Rural communities
Wisconsin ADRC Data Management Process Needs

- **Recruitment**
  - Demographics
  - Source of referral
  - Anonymous until consent

- **Screening / eligibility**
  - Multiple screening processes
  - Multiple protocol eligibility

- **Participant tracking**
  - Participation by protocol
  - Contacts by study coordinator

- **Research Data/Protocol Management**
  - Research administration
  - Protocol set-up / management
  - Visit tracking/data capture
  - Study data management
  - Cost of research visit
Wisconsin ADRC Data Management Process Requirements

- **Study Data Management**
  - Tracking / reporting
  - Analysis
  - Collaboration

- **Timeliness**
  - Study visit window
  - Data reporting window

- **NACC**
  - Uniform Data Set (UDS)
  - Neuropathology (NP)

- **Performance monitoring**
  - Recruitment
  - Study participation
  - Data integrity
Wisconsin ADRC Data Management Needs

Two distinct data management systems

Management of Participation

Management of Research Data
Wisconsin ADRC Data Management Solutions

- ADRC recruitment - Web-based Registry (REGGIE™)
  - Screening, Registration & Contact Management
  - Workflow Management
  - Recruitment Measurement & Reporting

- Research data - UW Institute for Clinical and Translational Research (ICTR) Web-based OnCore® database
  - Protocol Set-up & Management
  - Visit Tracking & Data Capture and Management
  - Data Reporting and Analysis

- Optimal use of each system
- Focus on workflow within each system
Development of Web-base Registry REGGIE™

‘Original’ ADRC database

- 2,000+ current/past participants
- No participant contact management workflow
- Limited participant screening information
- Limited ability for staff to collaborate
- Limited ability to query useful information for recruitment or identifying participation
Developing Registry Specifications

- Biostatistics & Data Management core met with Administrative and Clinical core staff biweekly / 4 months
  - Defined data needs
  - Defined registry specifications
- Biostatistics & Data Management core conducted assessment of options
  - Determined Customer Relationship Management (CRM) best fit contact management needs
- CRM database solution agreed to by Biostatistics & Data Management, Administrative and Clinical cores
Why Customer Relationship Management software?

- Volunteer participants are the “key” customers during the research process
- Streamlined and standardized contact and screening processes
- Cross-collaboration and participation
- Easier profiling and targeting
- Improved customer service and follow-up
- Business maturity of the CRM model
- Operational efficiency of the CRM model
Major Functions in Web-base Registry REGGIE™

- Web-based access
- Storage of contact and initial screening information
- Intuitive data-mining of contact and screening information
- Shared study recruitment workflow
- Activity coordination, planning and collaboration
- Shared communication and workflow scheduling
- “All-in-one” recruitment/screening/tracking
New WCMP Contact

Screening Script (PDF)

- create new -

SAVE  SAVE AND NEW  CANCEL

WCMP Contact Form

Today's Date: [ ] [ ] [ ] (clear)

1) Contacts:
- In person
- Phone Call
- Email
- Postal Mail
- Unknown

2) What is the main reason(s) for contacting the WCMP? (check all that apply)
- Interested in research for self
- Concerned about memory (self)
- Want more information about
- Other -- please specify:

3) Potential Participant:
- Self
- Loved One
- Both
- Unknown

SAVE
4) Does the potential Study Participant have a DIAGNOSED memory disorder?  
- Yes  - No  - Unknown  

5) Are you currently taking medication for a memory disorder?  
- Yes  - No  - Unknown/Refused
13) How did you hear about the WCOMP? (Check all that apply)

- Self
- Spouse/Partner
- Adult child
- Another research participant
- Friend/coworker/colleague
- UW/VA Memory Clinic Clinician
- Specialty Care Clinician
- Primary Care Provider
- Print Ad
- TV Ad
- Radio Ad
- Radio Interview
- TV Interview
- Newspaper interview or article
- Community Lecture (specify)
- WCOMP Lecture
- Flyer/Flyer/brochure
- Booth at a Community Event
- Email
- Website
- WCOMP (pharma study, ADCCS study, VA studies)
- WRAP
- VA Memory Clinic
- UW Memory Clinic
- MCW Memory Clinic
- WAD Dementia Diagnostic Network Clinic
- Community event/screening event (specify)
- Alzheimer's Association
- Area Agency on Aging
- EisnerCare
- Dr. Larry Sullivan- Milwaukee Memory Clinic
- Dr. Yucac- Dean Memory Clinic Madison
- Unknown/Refused
- Other (specify)
WCMP Participant ICF Outcome

a1) Outcome of first contact
- Eligible to continue
- Not eligible -- Age
- Not eligible -- Medical
- Not eligible -- Other

a2) Follow-up Required
- Yes
- No

a3) Interviewer (Last Name, First Name)

Obtain Consent (Must be eligible)
a4) Verbal consent read
- Yes
- No

a5) Participant verbal consent received
- Yes
- Refused consent -- Time Constraint
- Refused consent -- Not Interested
- Refused consent -- Reason Unknown
- Refused consent -- Other

(unselect)
a1) Outcome of first contact
- Eligible to continue
- Not eligible -- Age
- Not eligible -- Medical
- Not eligible -- Other

a2) Follow-up Required
- Yes
- No

a3) Interviewer (Last Name, First Name)

Obtain Consent (Must be eligible)

a4) Verbal consent read
- Yes
- No

a5) Participant verbal consent received
- Yes
- Refused consent -- Time Constraint
- Refused consent -- Not Interested
- Refused consent -- Reason Unknown
- Refused consent -- Other

Personal Data Form (Must have consent)

Participant(s) Name:
- Prefix
- First Name
- Middle Name
- Last Name
- Suffix
This contact does not currently belong to any groups.
New Membership

Member: Tom Mish

Membership Organization and Type:
- select -

Source:
- select -
ADRC
SHARP Drug: Simvastatin
Eli Lilly
PREDICT
Falls
Merit220
PIPR
SEAIRA Drug: Ramipril

IGIV Drug: Immune Globulin Intravenous
ELAN Drug: Bapineuzumab
TBIVA
WMAD
Eli Lilly Open Label Extension
Elan 301
Elan Open Label Extension
Elan 3001 Screen fails from 301
Active Recruitment Process
Wisconsin Brain Donor Program
### Membership Summary

<table>
<thead>
<tr>
<th>Members by Type</th>
<th>August – New/Renew (Last Month)</th>
<th>September – New/Renew (MTD)</th>
<th>2010 – New/Renew (YTD)</th>
<th>Current #</th>
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<tr>
<td>ADRC Clinical Core Member</td>
<td>6</td>
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<td>56</td>
<td>60</td>
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<td>SHARP Member</td>
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<td>0</td>
<td>0</td>
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<tr>
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<td>Falls Member</td>
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<td>2</td>
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<td>Eli Lilly Open Label Extension Member</td>
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<td>Elan 301 Member</td>
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<td>Elan Open Label Extension Member</td>
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<td>Elan 3001 Screen falls from 301 Member</td>
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<td>Active Recruitment Process Member</td>
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<td>ADRC IMPACT Member</td>
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<td><strong>6</strong></td>
<td><strong>132</strong></td>
<td><strong>199</strong></td>
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Wisconsin ADRC
Performance Monitoring

- recruitment / referral sources, reasons for contact
- # recruitment activities
- # participants from recruitment activities
- % recruitment / referral source categories
- % recruitment / referral source categories eligible / enrolled in ADRC
- % demographic categories
- % demographic categories eligible / enrolled in ADRC
- % demographic categories eligible / enrolled in other studies, protocols
- % recruitment / referral source categories active in studies
- participants recruited/eligible for ADRC, by category
- participants recruited/eligible for other studies, protocols
Wisconsin ADRC
Performance Monitoring

- # / % of participants continuing year-to-year, by category
- reasons for loss of participants, by category
- # participants active in other studies, protocols
- % recruitment / referral source categories eligible / enrolled in other studies, protocols
- demographics (age range, gender, ethnicity, race, zip code)

- # participants added per month, by category
- # completed visits, by category
- # completed data sets, by category
- average time, number of contacts needed to recruit into studies/protocols, by category
- # / % recruits active in ADRC, by category
- # / % recruits active in other studies, protocols
UW-Madison ICTR OnCore®

- CTSA research management system
- Secure web-based information management system
- Designed to help make clinical research efficient, well organized, and accurate throughout the life cycle of a protocol
- Currently ~ 200 protocols / 3,000 subjects across UW-Madison
OnCore® for ADRC Research Data

**Research Administration**
- Protocols
  - Basic Protocol Setup
  - Regulatory Tracking (e.g., IRB, CTRC)
  - Protocol activation
  - DSMC Reviews

- Subjects
  - Screening
  - Registration
  - Consenting
  - Eligibility
  - Subject Status
  - SAEs
  - Deviations

**Protocol Setup & Management**
- Calendars
  - Procedures & Evaluations
  - Initial & Follow Up Schedules
  - Visit Tolerances
  - Foot Notes

- eCRFs
  - Forms Design
  - Assign forms to studies

- Financials
  - Study Budgets
  - Negotiated Rates
  - SOC vs. Research
  - CMS compliance assistance
  - Payment Milestones

**Visit Tracking & Data Capture**
- Visits
  - Automated subject calendars
  - Visit & Procedure tracking
  - Additional Visits & Procedures
  - eCRF completion
  - Query resolution
  - Biospecimen tracking

**Study Data Management**
- Financial Management
  - Automated invoice items
  - Generate Invoices
  - Study Payment tracking
  - Unplanned visits & procedures
  - Exceptions
Wisconsin ADRC
OnCore® Data Management process

- Study Protocol set-up
- Subject registration
  - Identification/demographics
  - Consent
  - Eligibility
  - On-Study
- Visits
- eCRFs data entry
  - NACC (UDS and NP) and Wisconsin ADRC data
  - Biospecimen tracking

Tracks subjects from protocol screening through autopsy
Wisconsin ADRC
Summary of Lessons Learned

- Research participant is a “key” customer

- Collaboration across Cores is critical to success

- ‘New’ Center – advantage of learning from other Center experiences
  - Do’s and Don'ts
  - Wish lists
Wisconsin ADRC
Summary of Lessons Learned

Optimal use of each system

- Maximize data use within each process
- Minimize points of intersection / data crossover

Focus on workflow within each system

- Minimize data export / import
- Maximize data workflow within the system
Use of web-based technologies

- Maximize standardization across sites
- Minimize variations among users

Focus on Data needs across the systems
- Complementary functions
- Identify common elements
  - Same / similar format
  - ‘Minimum critical specifications’
Wisconsin ADRC Data Management Collaborators

- Biomedical Computing Group (BCG): Dave Towers, Tom Mish, Preethy Kaprakattu, David Tolmie, Debbie Yoshihara, Neeraja Deshpande, Ayuta Padhi, Vince Streif, Jenifer Kriplean, Christopher Harrison, Nevin Olson
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Wisconsin ADRC Data
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