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

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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

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Wisconsin ADRC Data Management Process Requirements

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

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

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

- **Performance monitoring**
  - Recruitment
  - Study participation
  - Data integrity

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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

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Development of Web-base Registry REGGIE^{TM}

'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

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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

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WISCONSIN COMPREHENSIVE MEMORY PROGRAM

Wisconsin Alzheimer's Disease Research Center

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New WCMP Contact

📄 Screening Script (PDF)

SAVE   **SAVE AND NEW**   **CANCEL**

▾ WCMP Contact Form

Today's Date: * [_____] 📅 (clear)

1) Contact: *

○ In person ○ Phone Call ○ Email ○ Postal Mail ○ Unknown   (unselect)

2) What is the main reason(s) for contacting the WCMP? (check all that apply)

☐ Interested in research for self   ☐ Interested in research for loved one
☐ Concerned about memory (self)   ☐ Concerned about memory of a loved one
☐ Want more information about [_____]
☐ Other -- please specify: [_____]

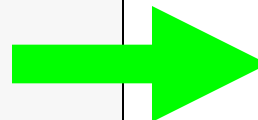**3) Potential Participant:** *

○ Self ○ Loved One ○ Both ○ Unknown   (unselect)

- create new - ▾

RECENT ITEMS

👤 Tom Mish

My Contact Dashboard

NEW INDIVIDUAL

First Name:
[_____]

Last Name:
[_____]

Email:
[_____]

SAVE

4) Does the potential Study Participant have a DIAGNOSED memory disorder? *

◉ Yes ○ No ◉ Unknown (unselect)

5) Are you currently taking medication for a memory disorder?

○ Yes ○ No ○ Unknown/Refused (unselect)

4) Does the potential Study Participant have a DIAGNOSED memory disorder? *

◉ Yes ○ No ○ Unknown (unselect)

Select all disorders that apply:

☐ Alzheimer's disease (AD)

☐ Mild Cognitive Impairment (MCI)

☐ Lewy Body dementia (LBD)

☐ Frontotemporal/Frontal lobe dementia (FTD, Primary Progressive Aphasia, Pick's disease, etc)

☐ Vascular dementia (VaD)

☐ Mixed dementia: (Specify causes (e.g., AD and VaD) [   ])

☐ Other (Specify: [   ])

☐ Unknown

☐ Refuse

5) Are you currently taking medication for a memory disorder?

○ Yes ○ No ○ Unknown/Refused (unselect)

13) How did you hear about the WCMP?(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) [_____]
- [ ] WCMP Lecture
- [ ] Flyer/Poster/Brochure
- [ ] Booth at a Community Event
- [ ] Email
- [ ] Website
- [ ] WCMP (pharma study, ADCS study, VA studies)
- [ ] WRAP
- [ ] VA Memory Clinic
- [ ] UW Memory Clinic
- [ ] MCW Memory Clinic
- [ ] WAI Dementia Diagnostic Network Clinic
- [ ] Community event/screening event (specify) [_____]
- [ ] Alzheimer's Association
- [ ] Area Agency on Aging
- [ ] Eldercare
- [ ] Dr. Larry Sullivan- Milwaukee Memory Clinic
- [ ] Dr. Yucas- 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 [   ]

(unselect)

a1) Outcome of first contact ▣

⦿ Eligible to continue
○ Not eligible -- Age
○ Not eligible -- Medical
○ Not eligible -- Other [   ]

(unselect)

a2) Follow-up Required ○Yes ○No   (unselect)

a3) Interviewer (Last Name, First Name) [   ]

Obtain Consent (Must be eligible)

a4) Verbal consent read

○Yes ○No   (unselect)

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 [   ]

(unselect)

a2) Follow-up Required ○ Yes ○ No   (unselect)

a3) Interviewer (Last Name, First Name) [   ]

Obtain Consent (Must be eligible)

a4) Verbal consent read

◉ Yes ○ No   (unselect)

a5) Participant verbal consent received

- ◉ Yes
- ○ Refused consent -- Time Constraint
- ○ Refused consent -- Not Interested
- ○ Refused consent -- Reason Unknown
- ○ Refused consent -- Other [   ]

(unselect)

Personal Data Form (Must have consent)

Participant(s) Name:

Prefix	First Name	Middle Name	Last Name	Suffix
[▼]	[ ]	[ ]	[ ]	[▼]

Tom Mish

Summary	Activities (1)	Memberships (0)	Groups (0)	Notes (0)	Tags (2)	Change Log (9)

ⓘ **This contact does not currently belong to any groups.**

Add to a group ▊

```
- select group -                    ▼   ADD
- select group -
ADNI-GO Recruitment
ADRC Imaging Team
ADRC-Mirriam
Administrators
Bridget Gregory
Caitlin Cleary
Jane Sachs
Jane-Mirriam
Kara P group 1
Laura Schmidt
Maia Wroblewski
New Coordinator
Outreach Activity Kari 5_6-2010
Recruitment Process Kari
Sharp Laura Jacobson
Vankee
WCMP imported contacts 5/28/2010
Zak Zugin
temp
```

CiviCRM ID: 5

is openly available under the GNU Affero General

View issues and report bugs.   Online docum

🔒 Tom Mish

SAVE   **SAVE AND NEW**   **CANCEL**

New Membership

Member   **Tom Mish**

Membership Organization and Type

| - select - ▼ | - select - ▼ |

- select -
ADRC
SHARP Drug:Simvastatin
Eli Lilly
PREDICT
Falls
Merit220
PIPR
SEAIRA Drug: Ramipril
VA Cooperative Drug: Vitamin E and/or memantine (Namenda)
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

Source

Join Date

Start Date

on Membership Type if you don't select a date.

End Date

ership Type if you don't select a date.

Status Override?

Send Confirmation and Receipt?

SAVE   **SAVE AND NEW**   **CAN**

New Activity

SAVE   **CANCEL**

New

Activity Type	- select activity - ▾
Added By *	Mish, Tom 🔍
With Contact	Olson, Nevin ✕
Assigned To	

You can optionally assign this activity to someone. Assigned activities will appear in their Activities listing at CiviCRM Home.
A copy of this activity will be emailed to each Assignee.

Subject	
Location	
Date *	09/09/2010 📅 Time * 11:30AM (clear)
Duration	Total time spent on this activity (in minutes).
Status *	Scheduled ▾
Details	

Scheduled
Completed
Cancelled
Left Message
Unreachable
Not Required

Advanced Search

Search Criteria

Find... ?

[   ]
Complete OR partial Contact Name.

[   ]
Complete OR partial Email Address.

Search Views [- default view - ▾]

SEARCH

CMS User? ○Yes ○No unselect
Does the contact have a Drupal Account?

Contact Type(s)
☐Individual
☐- WCMP Staff
☐- Mailing List Contact
☐- WCMP Contact
☐Household (Not Approved)
☐Study

Group(s)
☐Administrators
☐ADNI-GO Recruitment
☐ADRC Imaging Team
☐ADRC-Mirriam
☐Bridget Gregory
☐Caitlin Cleary
☐Jane Sachs
☐Jane-Mirriam
☐Kara P group 1
☐Laura Schmidt
☐Maia Wroblewski

Tag(s)
☐Not Interested In Research
☐Preferred Time of Contact
☐Prefers Afternoon Contact
☐Prefers AM Contact
☐Prefers PM Contact
☐Talk only to caregiver/spouse

Privacy
☐Do not phone ☐Do not email ☐Do not mail ☐Do not sms
☐Do not trade ☐Include contacts who have these privacy option(s). **?**

Preferred Communication Method
☐Phone ☐Email ☐Postal Mail ☐SMS ☐Fax

Contact Source [   ]

▸ Address Fields

▾ Custom Fields

▾ WCMP Contact Form

Today's Date: - From [   ] 📅 (clear) **To** [   ] 📅 (clear)

Contact: ○In person ○Phone Call ○Email ○Postal Mail ○Unknown
unselect

What is the main reason(s) for contacting the WCMP?
☐Interested in research for self   ☐Interested in research for loved one
☐Concerned about memory (self)   ☐Concerned about memory of a loved one
☐Want more information   ☐Other
☐*Check to match ANY; uncheck to match ALL*

CiviMember

Membership Summary ?

Members by Type	August — New/Renew (Last Month)	September — New/Renew (MTD)	2010 — New/Renew (YTD)	Current #
ADRC Clinical Core Member	6	1	56	60
SHARP Member	0	0	0	0
Eli Lilly Member	0	0	0	7
PREDICT Member	0	0	8	8
Falls Member	0	2	2	2
Merit 220 Member	0	0	0	0
PIPR Member	1	0	3	3
SEAIRA Member	3	2	10	10
VA Cooperative Member	0	0	0	0
IGIV Member	0	0	2	2
ELAN Member	0	0	0	0
TBIVA Member	0	0	0	0
WMAD Member	0	0	0	0
Eli Lilly Open Label Extension Member	0	0	0	0
Elan 301 Member	0	0	0	0
Elan Open Label Extension Member	0	0	0	0
Elan 3001 Screen fails from 301 Member	0	0	0	0
Active Recruitment Process Member	3	0	3	3
ADRC IMPACT Member	0	1	1	1
Brain Donor Program Member	23	0	47	103
Totals (all types)	**36**	**6**	**132**	**199**

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
- Data Monitoring
- Data Discrepancy Management
- Data Export for Analysis & Reporting

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

OnCore®

NEVIN OLSON (CRA_ASSIGNED ⌄) UW-Madison

My Profile   Log Off
Documentation   About

| My Console ▼ | Protocols ▼ | Reports ▼ | Subjects ▼ |

Subject Console

User: NEVIN OLSON ❓

Protocol No.: 1139

Protocol Status: OPEN TO ACCRUAL

Subject Status: ON STUDY

Subject MRN: 47689456

Subject Name: Abraham Simpson

Sequence No.: adrc00022

| Summary |
| Forms by Status |
| Forms By Visit |
| Demographics |
| Consent |
| Eligibility |
| On Study |
| Treatment |
| Follow Up |
| SAEs |
| Calendar |
| Additional Visits |
| Payments |
| Deviations |
| Documents/Info |
| Protocols |
| Subject MRN |
| Switch Subject |
| Type here to search ▼ |

Freeze Panes

Freeze Panes is currently supported on Microsoft Windows Internet Explorer 6+ browsers only.

Current Subject Calendar Version - V1

Procedure	Forms	Treatment					
		Screening 0@1Days	Baseline - AD/MCI/Cog Healthy 0:1@2Days		Annual Visits - AD/MCI/Cog Healthy 1:5@4Years		
		1	2	3	4	5	6
		Screening	Baseline	Biomarkers Visit	Annual Follow-up - Yr 1	Annual Follow-up - Yr 2	Annual Follow-up - Yr 3
Planned Date		04/26/2010	04/27/2010	04/28/2010	04/27/2011	04/26/2012	04/26/2013
Visit Status		Occurred	Occurred				
Visit Date		04/26/2010	04/27/2010				
ELIGIBILITY REVIEW (of Inclusion/Exclusion Criteria)	WADRC ScrV1	X					
INFORMED CONSENT PROCESS		X	X	X[1,AN]	X[AN]	X[AN]	X[AN]
CT ANGIO HEAD W & W/O CONTRAST CORE NEEDLE (CT), CT ANGIO HEAD W & W/O CONTRAST, IOHEXOL 60% 300 MG/ML 50 ML, NEEDLE SET (CT),							

Calendar Foot Notes

1.	Day 2 - Biomarkers Visit MRI and LP
2.	Community dwelling older adult cohort only
3.	IMPACT Control/Cohort Only
FV.	Follow-up Visit
IV.	Initial Visit
M1.	Mark this procedure as Not Applicable (NA) on the Subject Visit Update screen if it is not necessary to complete this form.
NP.	Put subject "On Follow-up" to trigger NACC NP form for completion
S1.	Biospecimen Collection: Whole Blood

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

Wisconsin ADRC
Summary of Lessons Learned

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

- Institute for Clinical and Translational Research (ICTR): Tracy Ohrt, Tamara Walker

- Biostatistics & Medical Informatics: Maritza Dowling, Rick Chappell, Jodi Barnet, Rachel Hunter-Merrill

- Wisconsin ADRC: Sanjay Asthana, Carey Gleason, Cindy Carlsson, Hanna Blazel, Amy Hawley, Kari Paterson, Tamara Markgraf, Jane Sachs, Jackie Lee, Heidi Walaski, Mirriam Rosen, Alyce Marsh

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  Biomedical Computing Group, All rights reserved

- OnCore® copyright 2001-2010
  PercipEnz Technologies, Inc. All rights reserved

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