

# An electronic data entry system: Experience in designing and implementing the system

**Roger A Mueller, BA**

**Mayo Clinic ADRC**

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# Mayo ADRC



**Rochester, MN**



**Jacksonville, FL**

# History of Mayo ADRC

- **1990 funded as ADCC**
- **1995 successful renewal**
- **1998 responded to RFA for ADRC's**
- **1999 funded as P50**
- **2004 renewed as P50**
- **2009 renewed as P50**
- **2014 anybody's guess**

# Current Projects

- **Mayo Clinic ADRC in MN and FL sites**
  - ~700 active subjects
  - 1700+ subjects enrolled since inception
  - ~250 UDS and UDS related subjects with autopsies
- **Subjects also participate in sub-studies**
  - ~1700 subjects with MR scans
  - ~200 subjects with PET scans
  - ~1700 subjects with blood samples
  - ~40 subjects with CSF draws

# Current & Future States

- **SAS database, 120 tables, 6000 variables with SAS interface**
- **Integrated custom infrastructure, tracking subjects end to end**
- **Paper-based geared for heads down data entry**
- **GOAL: Recreate infrastructure in Rave so schedulers, physicians, coordinators, and psychometrists all perform direct entry**

# External Warehouse Design

- **C1: Admin, Clinical, bios, imaging, etc.**
- **C2: Admin, Clinical, bios, imaging, etc.**
- **C3: Admin, Clinical, bios, imaging , etc.**
- **C4: Admin, Clinical, bios, imaging, etc.**
- **C5: Admin, Clinical, bios, imaging, etc.**
- **C6: Admin, Clinical, bios, imaging, etc.**
- **C7: Admin, Clinical, bios, imaging, etc.**

# Making our Goals Happen with an Integrated Design

- Divided our research into two parts
- Built Rave Master Track Registry for flexibility and tracking subjects on one or more studies: **Administration side**
- Built Rave individual research projects to collect specific research data: **Research side**
- Built custom function and web service infrastructure so multiple Rave projects can talk to each other



# Challenges

- **Rave technology for multi-project cross-talk available, but limited experience**
- **Design for entry vs. batch loading**
- **Master Track**
  - **Flexibility to add and close out sub-projects**
  - **Minimize where to change code when new studies are added**
- **Define a generic structure to which all research studies conform**



# What it took to make it work

- **On the Administration side**
  - 27 forms
  - 400 edit checks
  - 40 of 50 CFs for project cross-talk
- **On the ADRC Research side**
  - 71 forms
  - 2340 edit checks
  - 5 of 57 CFs for project cross-talk

# Administration Design Overview

<div> <div> </div> <div> ALZ1002 Master Track </div> <div>  Mayo Clinic </div> <div>  85638-ALZ </div> <div>  Demographics </div> </div>																																									
<div> <div>  85638-ALZ </div> <div> <div>Cycle 01</div> <div>Demographics</div> <div>Demographics Alias Ids</div> <div>Subject Characteristics</div> <div>Subject History</div> <div>Comments</div> </div> </div>	<div> <div> Mayo Clinic Number: 3745952 </div> <div> NACC Number: </div> <div> Date of Birth: 14 Feb 1928 </div> </div> <div> <div> BARD Number: </div> <div> Last Name: Mouse </div> <div> Gender: Male </div> </div> <div> <div> FL Fake MC Number: </div> <div> First Name: Mickey </div> </div>																																								
Draft has been published																																									
<div> <div> Subject: 85638-ALZ </div> <div> Page: Demographics </div> </div>																																									
<div> <div>Subject Summary</div> <div> Main Address Line 1: 100 Goofy Lane </div> <div> Main Address City: Orlando </div> <div> Main Address State: Florida </div> <div> Main Address ZipCode: 55555 </div> <div> Primary Phone Area: 555 </div> <div> Primary Phone Phone: 5555555 </div> <div> Cell Phone Area: </div> <div> Cell Phone Phone: </div> </div>	<table> <tr> <td>Title</td> <td>Mr.</td> <td></td> <td></td> </tr> <tr> <td>First Name</td> <td>Mickey</td> <td></td> <td></td> </tr> <tr> <td>Middle</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Last Name</td> <td>Mouse</td> <td></td> <td></td> </tr> <tr> <td>Suffix</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Date of Birth</td> <td>14 Feb 1928</td> <td></td> <td></td> </tr> <tr> <td>Death Status - Has subject died?</td> <td>No</td> <td></td> <td></td> </tr> <tr> <td>If Yes, Is Year of Death known?</td> <td></td> <td></td> <td></td> </tr> <tr> <td>If Year of Death known, Date of Death</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Gender</td> <td>Male</td> <td></td> <td></td> </tr> </table>	Title	Mr.			First Name	Mickey			Middle				Last Name	Mouse			Suffix				Date of Birth	14 Feb 1928			Death Status - Has subject died?	No			If Yes, Is Year of Death known?				If Year of Death known, Date of Death				Gender	Male		
Title	Mr.																																								
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# Administration Design Overview

ALZ1002 Master Track

Mayo Clinic

85638-ALZ

Cycle 01

Studies

Cycle 01

Studies

Phone Attempts (1)

Phone (1)

ADRC Visit (1)

MR Screening

MR Phone Attempts (1)

MR Phone (1)

MR Visit (1)

PET Screening

LP Screening

CRF History

85638-ALZ - Studies

85638-ALZ - MR Visit (1)

85638-ALZ - MR Phone (1)

85638-ALZ - MR Screening

85638-ALZ - ADRC Visit (1)

85638-ALZ - Phone (1)

85638-ALZ - Demographics

Mayo Clinic Number: 3745952

NACC Number:

Date of Birth: 14 Feb 1928

BARD Number:

Last Name: Mouse

Gender: Male

FL Fake MC Number:

First Name: Mickey

Subject: 85638-ALZ

Page: Studies - Cycle 01

Resp Sched Coord

Hackenmiller, Barb

Total Number Visits

0

Total Number UDS Visits

0

Total Num Accepted UDS Visits

0

#	Study	Packet	Baseline Visit	UDS Visit	UDS Accepted Visit	Tot Num Study Visits	popvisit	
1	ADRC	Full	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	0	No	
2	MR963-97	Full	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	0	No	
3	PET08-005553	Full	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	0	No	
4	LP10-001042	Full	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	0	No	

Add a new Log line Inactivate

# Administration Design Overview

Mayo Clinic Number: 3745952  
NACC Number:  
Date of Birth: 14 Feb 1928





BARD Number:  
Last Name: Mouse  
Gender: Male

Subject: 85638-ALZ  
Page: Subject History



#	Order ID	Cycle Number	Previous Date	Date Status Initiated	Study #	Study	Study Phase	Cycle Participation
1	<input type="text"/>	01	<input type="text"/> ... <input type="text"/>	27 Sep 2012	3	ADRC	Pre-Consent Phone	Active
2	<input type="text"/>	01	<input type="text"/> ... <input type="text"/>	27 Sep 2012	25	MRI963-97	Screening	Active
3	<input type="text"/>	01	<input type="text"/> ... <input type="text"/>	27 Sep 2012	28	PET08-005553	Screening	Not Yet Determined
4	<input type="text"/>	01	<input type="text"/> ... <input type="text"/>	27 Sep 2012	26	LP10-001042	Screening	Not Yet Determined
5	<input type="text"/>	01	<input type="text"/> ... <input type="text"/>	27 Sep 2012	3	ADRC	Visit	Scheduled
6	<input type="text"/>	01	<input type="text"/> ... <input type="text"/>	27 Sep 2012	25	MRI963-97	Phone	Active
7	<input type="text"/>	01	<input type="text"/> ... <input type="text"/>	27 Sep 2012	25	MRI963-97	Visit	Scheduled

Add a new Log line Inactivate


# Research Design Overview

 ALZ1103 ADRC-MN  Mayo Clinic  85638-ALZ  Add Patient















Subject: 85638-ALZ  
Page: Add Patient

Enter Mayo Clinic Number ONLY and then save form.

Mayo Clinic Number 3745952  

Verify the following patient information AFTER Mayo Clinic Number has been entered and form has been saved.  
If any changes are made, be sure to also update ALZ1002 Master Track.

Title	Mr. 	 
First Name	Mickey 	 
Middle		 
Last Name	Mouse 	 
Suffix		 
Date of Birth	14 Feb 1928 	 
Gender	Male 	 

# Research Design Overview

ALZ1103 ADRC-MN		Mayo Clinic	85638-ALZ	Cycle 01	Post-Visit Summary
Mayo Clinic Number: 3745952		FL Fake MC Number:		NACC Number:	
Last Name: Mouse		First Name: Mickey		Date of Birth: 14 Feb 1928	
Gender: Male					
Subject: 85638-ALZ					
Page: Post-Visit Summary - Cycle 01					
Section 2: To be recorded after the subject is done with the visit.					
Non-psychometric validity: 1=Satisfactory					
Section 3: To be recorded after all possible data is collected and entered for this visit.					
Is Visit Complete?					
Were there any Adverse Events? 1=No Adverse Events					

# Research Updating Master Track

ALZ1002 Master Track		Mayo Clinic		85638-ALZ		Subject History		
Mayo Clinic Number: 3745952				BARD Number:				
NACC Number:				Last Name: Mouse				
Date of Birth: 14 Feb 1928				Gender: Male				
Subject: 85638-ALZ Page: Subject History								
#	Order ID	Cycle Number	Previous Date	Date Status Initiated	Study #	Study	Study Phase	Cycle Participation
1	<input type="text"/>	01	<input type="text"/> ... <input type="text"/>	27 Sep 2012	3	ADRC	Pre-Consent Phone	Active
2	<input type="text"/>	01	<input type="text"/> ... <input type="text"/>	27 Sep 2012	25	MRI963-97	Screening	Active
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7	<input type="text"/>	01	<input type="text"/> ... <input type="text"/>	27 Sep 2012	25	MRI963-97	Visit	Scheduled
8	<input type="text"/>	01	<input type="text"/> ... <input type="text"/>	27 Sep 2012	3	ADRC	Visit Summary (from study)	Active



# Feedback & Lessons Learned

- **Sporadic slowness**
- **Larger computer monitors beneficial**
- **Most CRA questions pertain to training, dealing with change, and getting used to a new system**
- **CRAs suggested few form and field tweaks**
- **Few edit check glitches**
- **Overall positive feedback by users**

# Feedback & Lessons Learned

- **Upfront work of interviewing stakeholders to determine workflow processes**
- **Testing, testing, and more testing**
- **Training, training, and more training**
- **We contributed to Mayo's new institutional platform for research data management across the enterprise**
- **Input and flexibility of Lilah Besser and Leslie Phillips from NACC re: UDS electronic forms**

**Thank You!!**

**Questions?**