

Alzheimer's Mapping Project

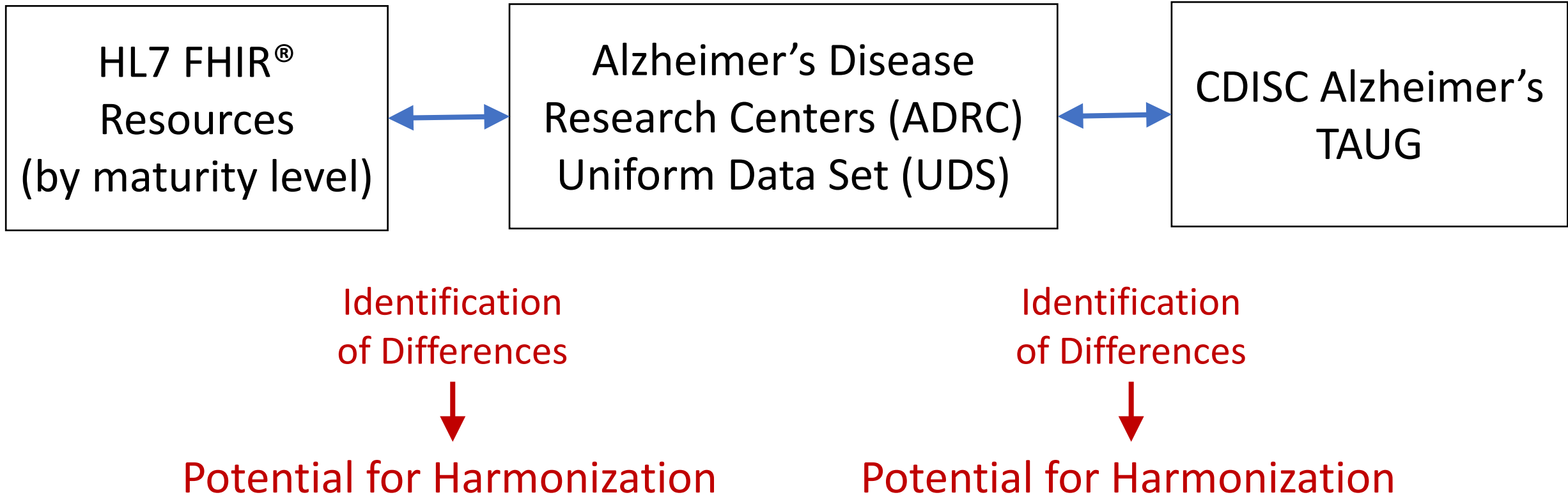
A “quick” but potentially important project.

Project Introduction, Update, and Discussion

Meredith Nahm Zozus, PhD

Professor, Div. Chief and Director of Clinical Research Informatics
Keith M. Orme and Pat Vigeon Orme Endowed Chair in Alzheimer's and Neurodegenerative Diseases
University of Texas Health Sciences Center San Antonio
Joe R. and Teresa Lozano Long School of Medicine

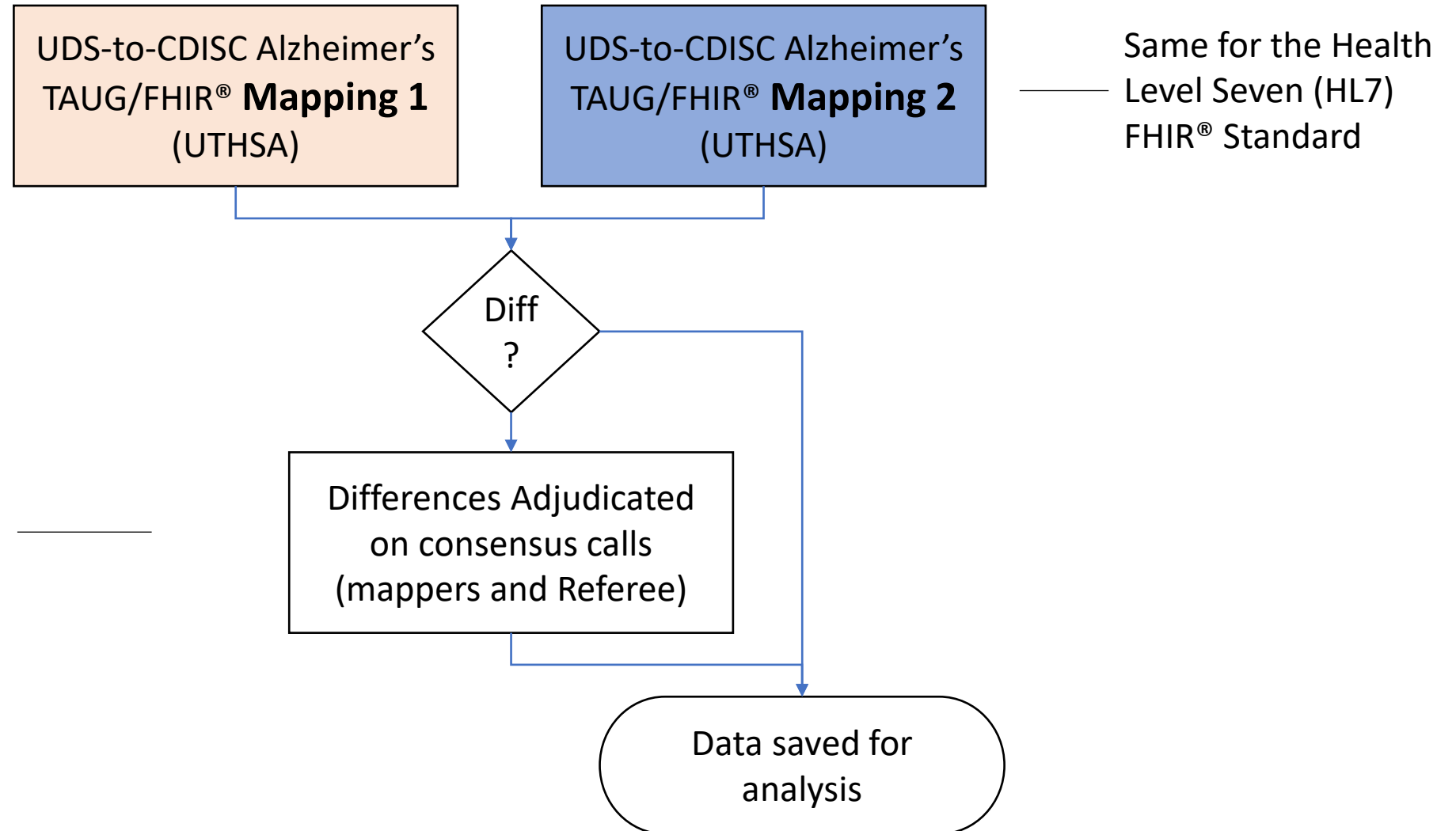
The Project



Why is the project being pursued?

- The ADRC network is over 30 years old and collects common, longitudinal data annually on Alzheimer's patients.
 - Clinical data, Cognitive assessment, Imaging, and Biological samples
- The common data elements (Uniform Data Set – UDS) has undergone its 4th major revision
- The CDISC Alzheimer's TAUG development did not, that we know of, include the ADRC data elements. Even if it did, the UDS revision needs to be assessed.
- Identifying opportunities for possible harmonization could be impactful.
 - e.g., may help assess post-market safety and even efficacy toward slowing cognitive decline or functional progression

Mapping Process Detail



Differences adjudicated by experts in the CDISC and FHIR® standards.

FHIR and CDISC Adjudicated Mapping Results

Packet	Number of Data Elements	FHIR® Mapping IRR n (%)	FHIR® Mapping Rate n (%)	CDASH Domain Mapping IRR (%)	CDASH Domain Mapping rate n (%)	CDASH Data Element Mapping IRR (%)	CDASH Data Element Mapping rate n (%)
UDS IVP	963	87%	407 (42%)	98%	934(97%)	96%	934(97%)
UDS FVP	893	83%	403 (45%)	98%	859(96%)	97%	859(96%)
UDS TIP	994	85%	437 (44%)	99%	936(94%)	98%	936(94%)
UDS FIP	850	82%	350 (41%)	97%	790(93%)	97%	790(93%)
UDS 4	883	86%	361 (41%)	98%	837(95%)	97%	837(95%)
FTLD TVP	342	57%	75 (22%)	100%	342 (100%)	100%	342 (100%)
FTLD TFP	346	57%	75 (22%)	100%	346(100%)	100%	346(100%)
LBD IVP	285	53%	116 (38%)	100%	285(100%)	100%	285(100%)
LBD FVP	286	58%	129 (42%)	100%	286(100%)	100%	286(100%)
CLD	31	45%	4 (13%)	100%	31(100%)	100%	31(100%)
AD	11	100%	3 (27%)	64%	10(91%)	64%	10(91%)
COVID-19	70	94%	55 (79%)	100%	64(91%)	100%	64(91%)
Total	5,954	79%	2,399 (40%)	98%	5,776(96%)	98%	5,776(96%)

UDS A5

#	Variable / Field Name	Field Label <i>Field Note</i>	Field Attributes (Field Type, Validation Choices, Calculations, etc.)	FHIR	Resource	Data Element	DE Definition
483	cvangio	2c. Angioplasty / endarterectomy / stent	radio (Matrix), Required	Y	Condition/Procedure(ZW)	code	Identification of the condition, problem or diagnosis. The specific procedure that is performed. Use text if the exact nature of the procedure cannot be coded (e.g. "Laparoscopic Appendectomy").(ZW)
			0 0 Absent				
			1 1 Recent/Active				
			2 2 Remote/Inactive				
			9 9 Unknown				
484	cvbypass	2d. Cardiac bypass procedure	radio (Matrix), Required	Y	Condition/Procedure(ZW)	code	Identification of the condition, problem or diagnosis. The specific procedure that is performed. Use text if the exact nature of the procedure cannot be coded (e.g. "Laparoscopic Appendectomy").(ZW)
			0 0 Absent				
			1 1 Recent/Active				
			2 2 Remote/Inactive				
			9 9 Unknown				
485	cvpacdef	2e. Pacemaker and/or defibrillator	radio (Matrix), Required	Y	Condition/Procedure(ZW)	code	Identification of the condition, problem or diagnosis. The specific procedure that is performed. Use text if the exact nature of the procedure cannot be coded (e.g. "Laparoscopic Appendectomy").(ZW)
			0 0 Absent				
			1 1 Recent/Active				
			2 2 Remote/Inactive				
			9 9 Unknown				
488	cvhvalve	2h. Heart valve replacement or repair	radio (Matrix), Required	Y	Condition/Procedure(ZW)	code	Identification of the condition, problem or diagnosis. The specific procedure that is performed. Use text if the exact nature of the procedure cannot be coded (e.g. "Laparoscopic Appendectomy").(ZW)
			0 0 Absent				
			1 1 Recent/Active				
			2 2 Remote/Inactive				
			9 9 Unknown				

CDASH UDS A5

507	diabetes	<p><i>Section Header: 5. Medical conditions if any of the conditions still require active management and/or medications, please select "Recent/Active."</i></p> <p>5a. Diabetes</p> <p>(If absent or unknown, SKIP TO QUESTION 5b)</p>	radio, Required		MH	MHCAT	MH	MHDECOD	F
			0 0 Absent						F
			1 1 Recent/Active						
			2 2 Remote/Inactive						
			9 9 Unknown						
		Custom alignment: LV							
508	diabtype	5a1. If Recent/active or Remote/inactive, which type?	radio, Required		MH	MHTERM	MH	METERM	
	Show the field ONLY if: [diabetes] = '1' or [diabetes] = '2'		1 1 Type 1						
			2 2 Type 2						
			3 3 Other type (diabetes insipidus, latent						
			9 9 Unknown						

CDASH UDS A5 adjudication

Medical conditions

If any of the conditions still require active management and/or medications, please select "Recent/active."

FAOBJ=DIABETES
FATESTCD=OCCUR (Y when ABSENT selected, N when RECENT/ACTIVE or REMOTE/INACTIVE selected)
FATEST=OCCURANCE

FAOBJ=DIABETES
FATESTCD=NCF (?)
FATEST=ABSENT/RECENT-INACTIVE/REMOTE-INACTIVE

Diabetes

MHTERM=DIABETES
MHPRESP=Y

MHOCCUR =Y when ABSENT selected, N when RECENT/ACTIVE or REMOTE/INACTIVE selected

when MHOCCUR=Y, MHENRTPT
"RECENT/ACTIVE"="ONGOING"
"REMOTE/INACTIVE"="BEFORE"
MHENTPT=visit date

- Absent
- Recent/active
- Remote/inactive
- Unknown

(asked in the form of --NCF, which would be okay if this were an intervention)
ABSENT = NEVER
RECENT/ACTIVE = CURRENT
REMOTE/INACTIVE = FORMER

If Recent/active or Remote/inactive, which type?

MHTERM

- Type 1
- Type 2
- Other type (diabetes insipidus, latent autoimmune diabetes/type 1.5, gestational diabetes)
- Unknown

Things to Consider

1. Questionnaires may “map” but they wont be available unless they are actually in the EHR
2. FHIR® Mapping results reflect presence of a structured field in the standard with which EHR data may be associated
 - An EHR vendor may not map anything to it
 - Facilities, specialties and providers may not use the field that maps to the FHIR® resource; we observed a ~10% variability among three sites where we mapped three studies.
 - THUS - mapping should be repeated at sites
3. Data may not be complete or of acceptable quality
 - These should be measures at sites
4. Sites may differ wrt participants actually being patients at the facility. The care relationship with a participant impacts the type and extent of data available from the EHR UNLESS sites choose to document research visits in the EHR .

Big Thank You To Those Who Worked on This !

- Helen Foster, UTHSA
- Gary Walker, CDISC
- Bess LeRoy, CDISC
- Rhonda Facile, CDISC
- Zhan Wang, UTHSA
- Kayla Torres, UTHSA
- Maryam Garza, University of Arkansas for Medical Sciences