

PRECISI NALS

Dataset, Usability and Process - Developing an Interdisciplinary, Multi-modal Data Collection Tool and Platform for a Rare Disease

> Sinead Impey, Jonathan Turner, et al. ADAPT Centre, Trinity College Dublin jonathan.turner@adaptcentre.ie













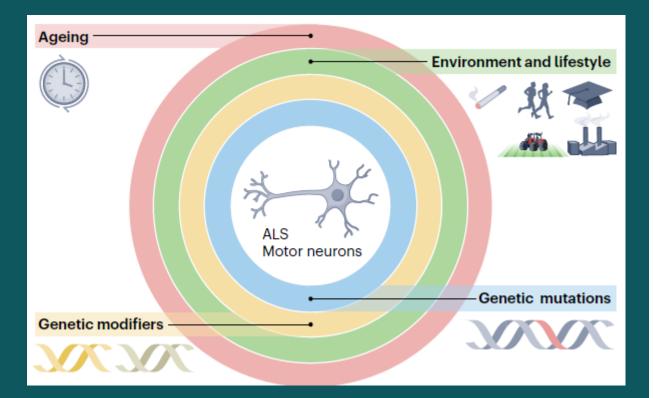
Jonathan Turner

- Jonathan is a Research Fellow in The ADAPT Centre, Trinity College Dublin, working on the Precision ALS project.
- He was awarded a PhD by City, University of London, in 2019 for work applying machine learning methods to longitudinal health records for predicting likelihoods of future health events.
- Previously, Jonathan had spent a number of years in the NHS in the UK as a medical physicist and systems analyst, working in diagnostic imaging, PACS, and hospital information systems management, and as Principal Evaluator in the PACSnet device evaluation group funded by the MHRA and NICE.
- He is a Fellow of the Faculty of Clinical Informatics, a Member of the Institute of Physics and a Member of the Institute of Physics and Engineering in Medicine.



Amyotrophic Lateral Sclerosis (ALS)

- An incurable progressive neurodegenerative disease responsible for up to 10,000 deaths per year in Europe.
 - A lifetime risk of 1:400.
 - The most common form of the motor neuron diseases.
 - But still a 'rare disease'.
- Most (> 90%) cases of ALS have no known cause; the remaining cases have a genetic cause.
- To understand the disease, its heterogeneity and its costs requires collaboration between clinicians and data scientists and large datasets.



from Akçimen F, Lopez ER, Landers JE, Nath A, Chiò A, Chia R, Traynor BJ. Amyotrophic lateral sclerosis: translating genetic discoveries into therapies. Nat Rev Genet. 2023 Sep;24(9):642-658

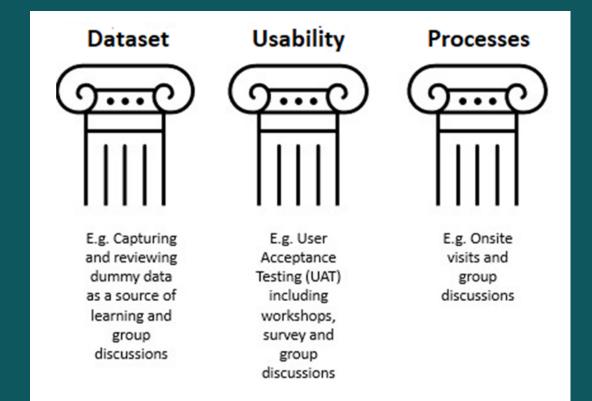
The Precision ALS Project



- A partnership between nine clinical sites, industry partners and researchers.
- Aims of this project include the development of a data collection tool, and an interdisciplinary data platform to gather, share and analyse multi-modal data.
- This presentation will focus on the development of the data collection tool.

Requirements gathering: the three pillars

- What are the requirements for the data collection tool?
- Requirements gathering focused on the needs of clinicians, data collectors and analysts.
- **Pillar 1, "Dataset":** content requirements for the data collection tool.
- **Pillar 2, "Usability":** requirements for the workflow through the data collection tool.
- **Pillar 3, "Processes":** requirements relating to the flow of data into the collection tool from the various data sources.



Requirements gathering 1: dataset

- Fields to be used in the data collection were identified.
 - Expert sources used for identification of these fields: clinicians specialising in ALS, data analysts, individual partner sites.
- Options within those fields were identified for inclusion on a paper worksheet.
 - This worksheet was used as a prototype for the tool.
 - For example, participants were to be questioned about their history of taking ALS symptomatic medications; a list of possible medications was included in the data collection tool as options from which the data collector could select appropriately.

Requirements gathering 2: usability

- The data collection tool is intended to be used in a variety of settings, including: faceto-face with participants and/or their carer(s); in telephone interviews; or for data entry from existing records.
 - In each scenario, the tool must be usable efficiently and accurately by the data collector.
- Representatives from each collection site were given a complete walkthrough of the collection tool.
 - Users then had the opportunity to explore the tool independently.

Requirements gathering 3: process

- Understanding the current processes and associated actors, both human and technological, involved in data collection.
- Avoid inefficient or impractical working practices.
- Existing data collection processes were examined for roles of actors involved in the collection process, in particular:
 - the role of data collectors; registration of participants; clinical coding systems used; information systems used; remote monitoring of participants.
- A research process fitting in to clinical processes.
 - Minimise impact on clinical work.

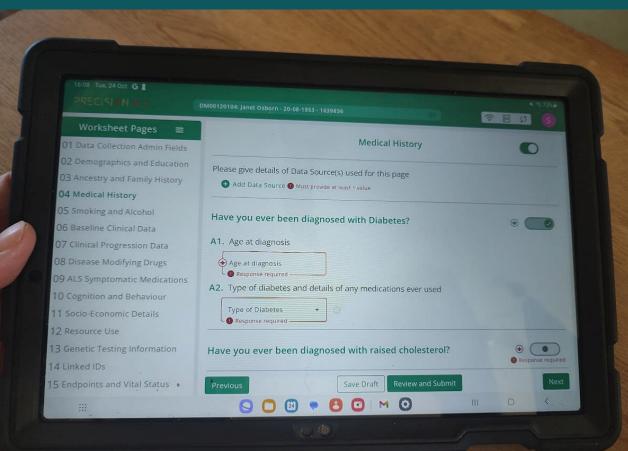
Results: requirements

- Use of the three pillars for requirements gathering was successful.
- From Pillar 1, dataset, an agreed dataset was identified.
- Pillar 2, usability, identified functions to improve engagement; results of a user survey are shown.
 - A user survey was completed by each site member, 13 users in total, using version 3 of the Post-Study System Usability Questionnaire (PSSUQ).
- Pillar 3, process, identified the people and systems currently used at data collection sites and how these actors could be replicated in the collection tool.

Question	Question text	Average
number		Score
1	Overall, I am satisfied with how easy it is	2.2
1	-	2.2
	to use the system	1 1
-		<u> </u>
2	It was simple to use this system	2.2
		1 1
3	I was able to complete the tasks and	2.4
	scenarios quickly using this system	
4	I felt comfortable using this system	2.6
5	It was easy to learn to use this system	2.3
6	I believe I could become productive	2.0
10	quickly using this system	
	durckly asing this system	1 1
7	The system gave error messages that	3.1
1		
	clearly told me how to fix problems	
8	Whenever I made a mistake using the	2.7
•		2.1
	system, I could recover quickly and easily	
9	The information (such as SOP) provided	2.3
	with this system was clear	
	numerous Particle 1.4	
10	It was easy to find the information I	2.0
	needed	1 1
11	The information was effective in helping	2.3
	me complete the tasks and scenarios	1 1
		<u> </u>
12	The organization of information on the	1.9
	system was clear	1 1
13	The interface was pleasant	2.0
		1000 C
14	I like using the interface of this system	2.2
15	The system has all the functions and	2.7
	capabilities I expect it to have	
	coparatives r expect it to have	
16	Overall, I am satisfied with this system	2.0
3083		
	Overall PSSUQ score	2.3
	ore on Passed score	
	System usefulness	2.3
	System userumess	2.5
	Information and Stu	24
	Information quality	2.4
	Interface and Day	1.2.2
	Interface quality	2.3

Application development

- An Android tablet-based application approach.
 - To ensure portability.
 - To enable operation without a working internet connection.
- Development carried out in-house in the ADAPT Centre at Trinity College Dublin.
 - The development team met regularly with clinicians and data analysts to ensure that the developed tool met their needs.
- The application was developed using the Kotlin programming language in Android Studio.
- Visits to data collection sites.
 - Revisit the PSSUQ.



Results: data collection tool

- The initial version of the data collection tool was first used in a clinical setting in August 2023 at one site.
- Further sites started data collection in September 2023. Four sites are now 'live'.
- On-going refinement integrating user feedback.

21:01 Wed, 16 Aug	© 50% DM00120100: John Doe - 25-01-1957 - 2673612
Worksheet Pages \equiv	Clinical Progression Data
01 Data Collection Admin Fields02 Demographics and Education03 Ancestry and Family History	Please give details of Data Source(s) used for this page Add Data Source ① Must provide at least 1 value
04 Medical History 05 Smoking and Alcohol 06 Baseline Clinical Data	Was Weight assessed on this occasion?
00 Baseline Clinical Data	Interventions
08 Disease Modifying Drugs 09 ALS Symptomatic Medications	4. Gastrostomy in situ
10 Cognition and Behaviour 11 Socio-Economic Details	5. Parenteral Nutrition 6. Non-invasive Ventilation
12 Resource Use Questionnaire 13 Genetic Testing Information	 Setup Date Response required Response required
14 Linked IDs 15 Endpoints and Vital Status	Previous Save Draft Review and Submit Next

Conclusions and future work

- A set of requirements for the development of a data collection tool can be constructed from the requirements of different groups of interested parties.
- The success of the developed tool is dependent on regular communication between these parties and the technical development team.
- Future work has three main strands.
 - Development and refinement of the data collection tool will continue.
 - Development of the data platform infrastructure will commence.
 - Extending the data collection tool for a multiple sclerosis project.

Acknowledgements

- Authors: Sinéad Impey, Jonathan Turner, Frances Gibbons, Anthony Bolger, Gaye Stephens, Lucy Hederman, Ciara O'Meara, Ferran De La Varga, John Kommala, Matthew Nicholson, Daniel Farrell, Emmet Morrin, Miriam Galvin, Mark Heverin, Éanna Mac Domhnaill, Robert McFarlane, Dara Meldrum, Deirdre Murray, Orla Hardiman
- This work is funded by the Science Foundation Ireland grant SP20/SP/8953. Professor Hardiman's work is also funded from grants 16/RC/3948 and 13/RC/2106_P2.

PRECISI NALS

More information: www.precisionals.ie

info@precisionals.ie

• jonathan.turner@adaptcentre.ie

Trinity College Dublin