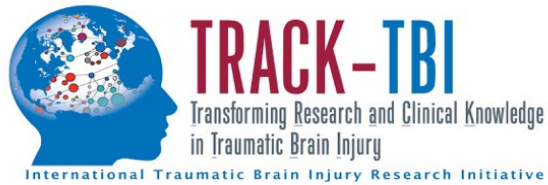


Examples of TBI Learning Health Systems



TRACK-TBI



Joseph T. Giacino, PhD
Professor of Physical Medicine and Rehabilitation
Spaulding Rehabilitation Hospital
Harvard Medical School
Boston, MA USA

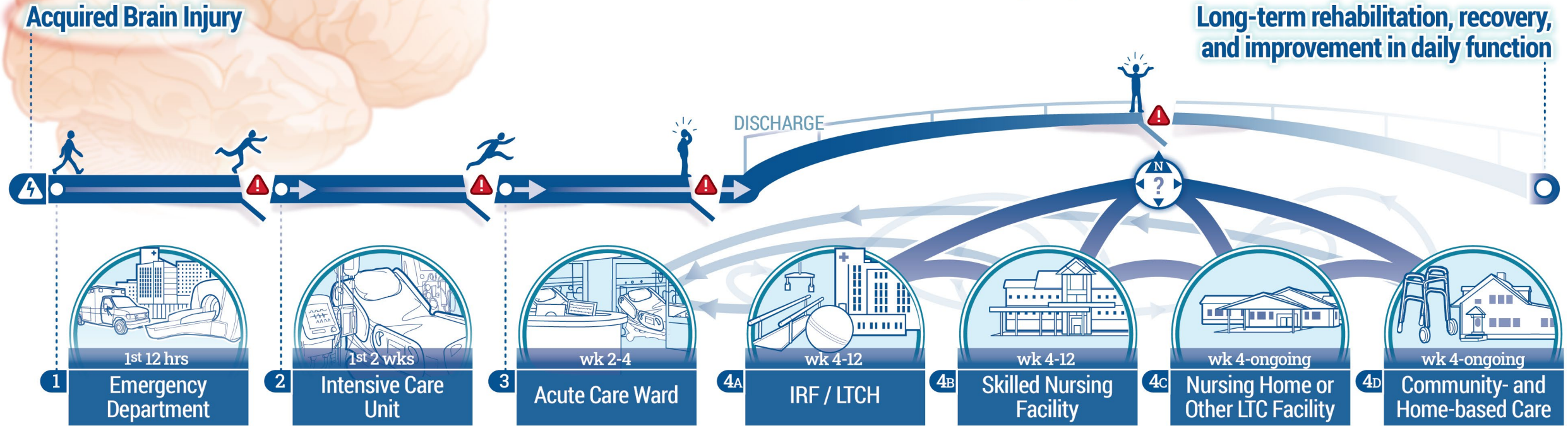


Department of Physical Medicine & Rehabilitation
Harvard Medical School

Spaulding Rehabilitation Hospital
Massachusetts General Hospital
Brigham & Women's Hospital

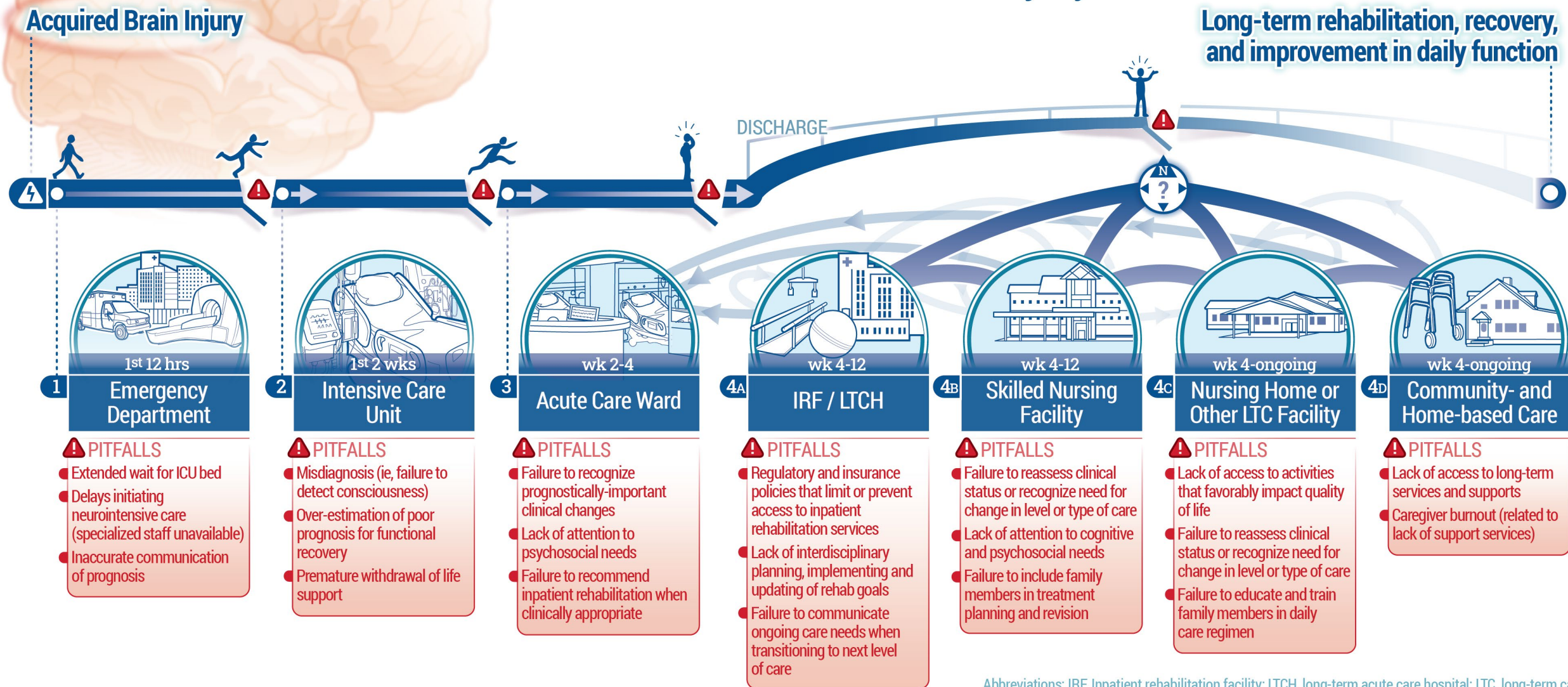


Preventing Health Service Delivery Pitfalls for Persons with Severe Brain Injury



Abbreviations: IRF, Inpatient rehabilitation facility; LTCH, long-term acute care hospital; LTC, long-term care.

Preventing Health Service Delivery Pitfalls for Persons with Severe Brain Injury



Abbreviations: IRF, Inpatient rehabilitation facility; LTCH, long-term acute care hospital; LTC, long-term care.

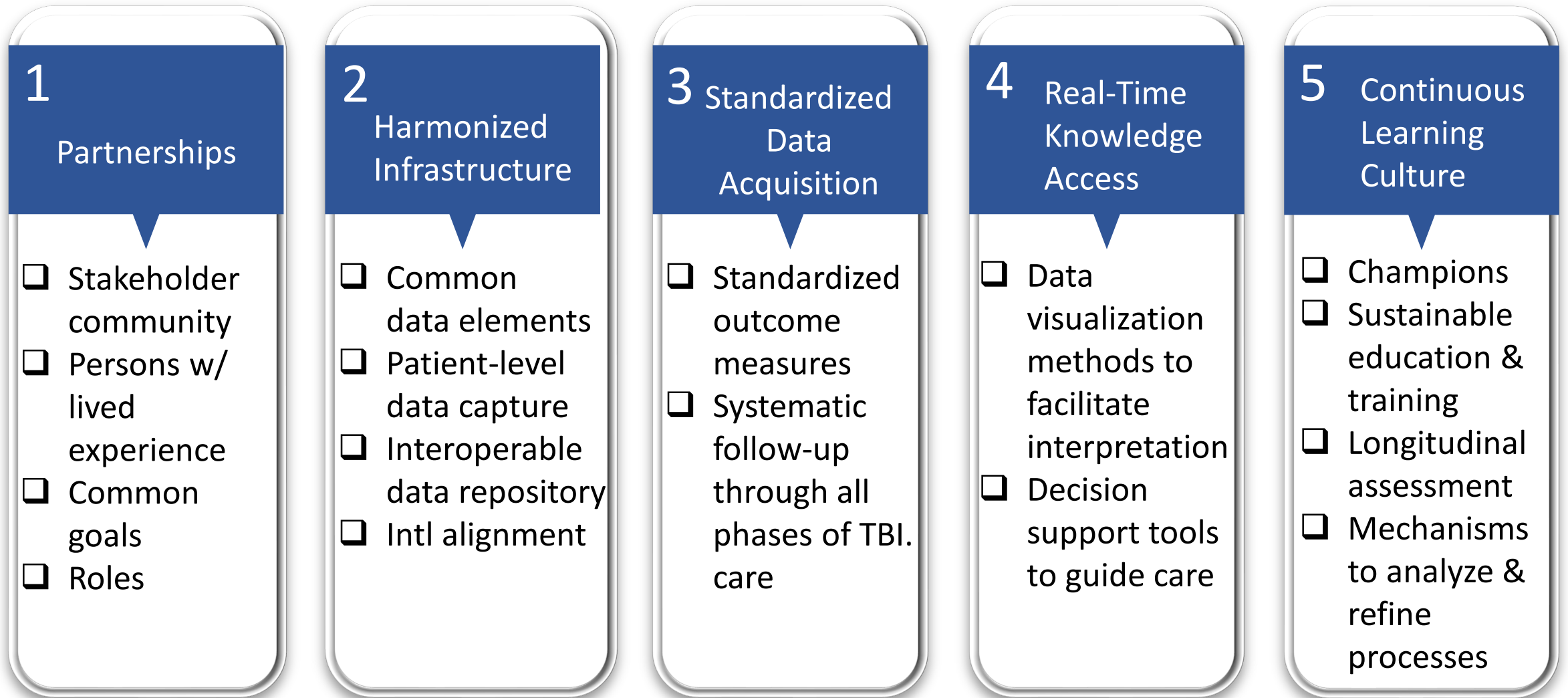
Learning Health System

“A health system in which internal data and experience are systematically integrated with external evidence, and that knowledge is put into practice.”



Feedback cycle for learning and improvement

Necessary (not sufficient) components of a TBI LHS



(IOM, 2007; NASEM, 2016; AHRQ, 2019; NASEM 2022)

What type of questions should a TBI LHS be able to answer?

1. *Diagnostic:* Which performance-based TBI assessment measures accurately detect mild TBI in adults within the first 48 hours of injury?
2. *Prognostic:* Which TBI endophenotypes, identified at 1-month post-injury, are most likely to remain permanently dependent on others for ADLs?
3. *Treatment:* What treatment is most effective for post-traumatic fatigue persisting longer than 12 weeks after mild to moderate TBI?

TRACK-TBI as a Learning Health System



Administrative PI
Geoff Manley, MD, PhD



1. Baylor College of Medicine/ TIRR Memorial Hermann
2. Denver Health Medical/ Craig Rehabilitation
3. Emory University
4. Hennepin County Medical Center
5. Indiana University
6. Medical College of Wisconsin
7. Spaulding Rehabilitation Hospital/ Massachusetts General Hospital
8. University of California, San Francisco
9. University of Cincinnati
10. University of Maryland
11. University of Miami
12. University of Pennsylvania
13. University of Pittsburgh
14. University of Utah Health Care
15. University of Washington
16. UT Austin-Seton
17. UT Health Houston
18. UT Southwestern
19. Virginia Commonwealth University



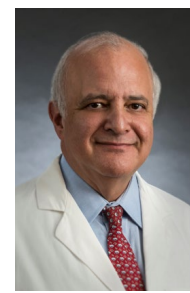
Clinical

C. Robertson- Baylor
D. Okonkwo- UPitt



Outcomes

J. Giacino- Harvard
M. McCrea- MCW



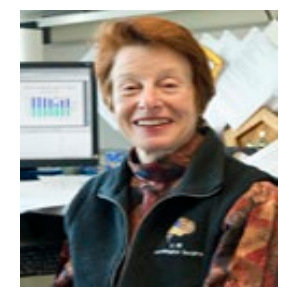
Biomarkers

R. Diaz-Arrastia-UPenn
K. Wang- U FL



Imaging

P. Mukherjee- UCSF



Biostatistics

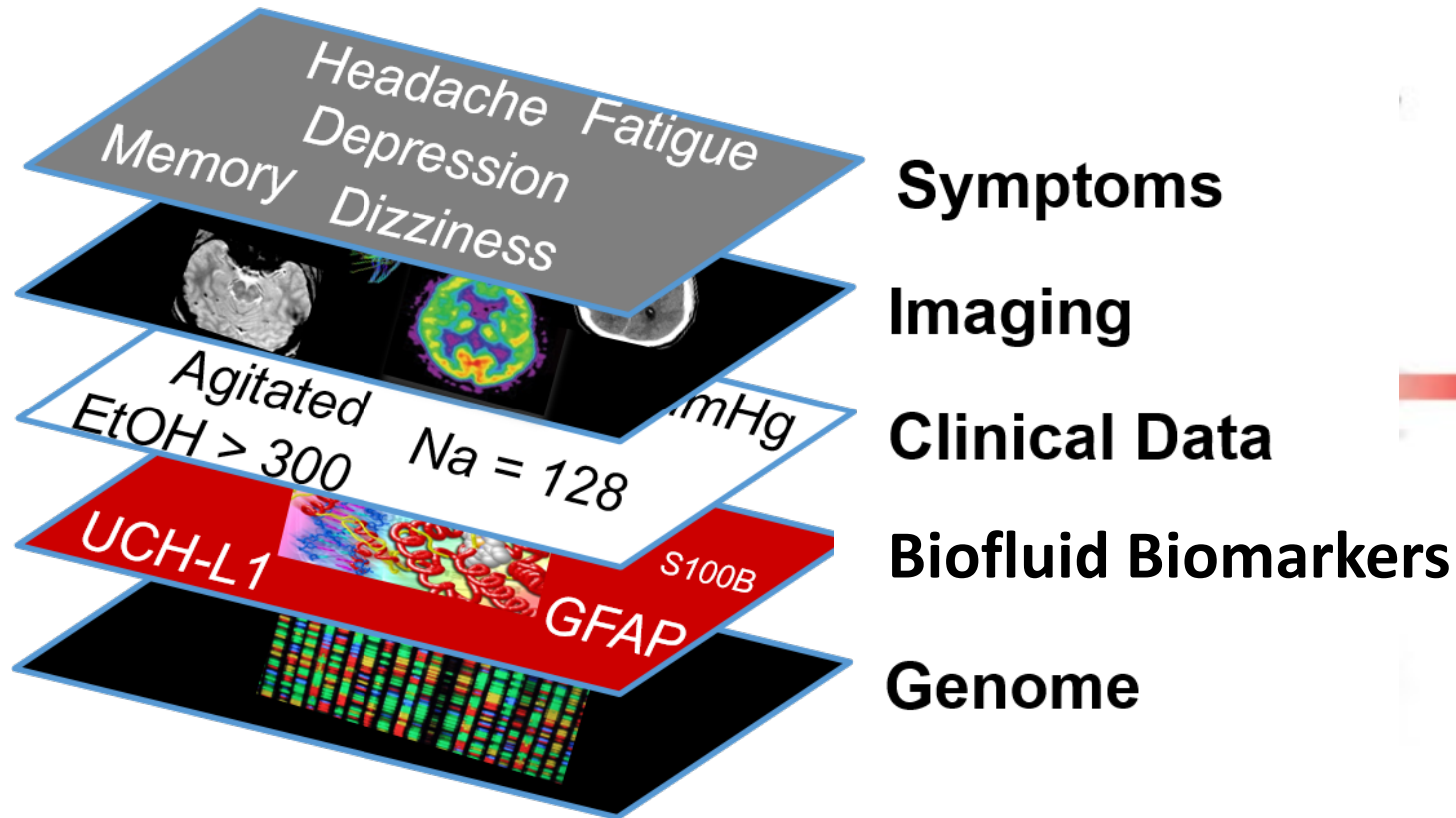
N. Temkin- UW

TRACK-TBI Aims

1. Create an “Information Commons” to promote collaboration and accelerate TBI research
2. Improve TBI diagnosis and classification/taxonomy
3. Improve TBI outcome assessment
4. Identify the health and economic impact of mild TBI

Objective

Precision Neuroscience → Personalized Care



Approach



TRACK-TBI

Transforming Research and Clinical Knowledge in Traumatic Brain Injury

International Traumatic Brain Injury Research Initiative



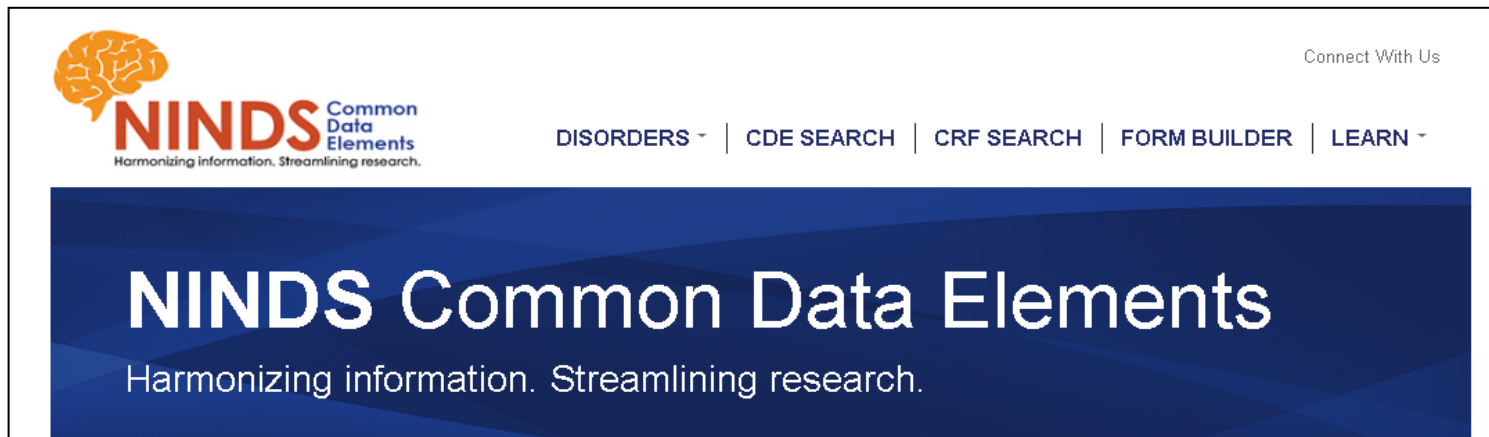
CENTER-TBI

Collaborative European NeuroTrauma Effectiveness Research in TBI
A 2020 vision: Generating knowledge for improving TBI outcomes

1

Partnerships

- ☐ Stakeholders
- ☐ Common aims
- ☐ Persons w/ lived experience



NINDS CDE Program Officer:

- Carolina Mendoza-Puccini, MD

NINDS Team:

- Nsini Umoh, PhD
- Hibah Awwad, PhD

Steering Committee Co-Chairs:

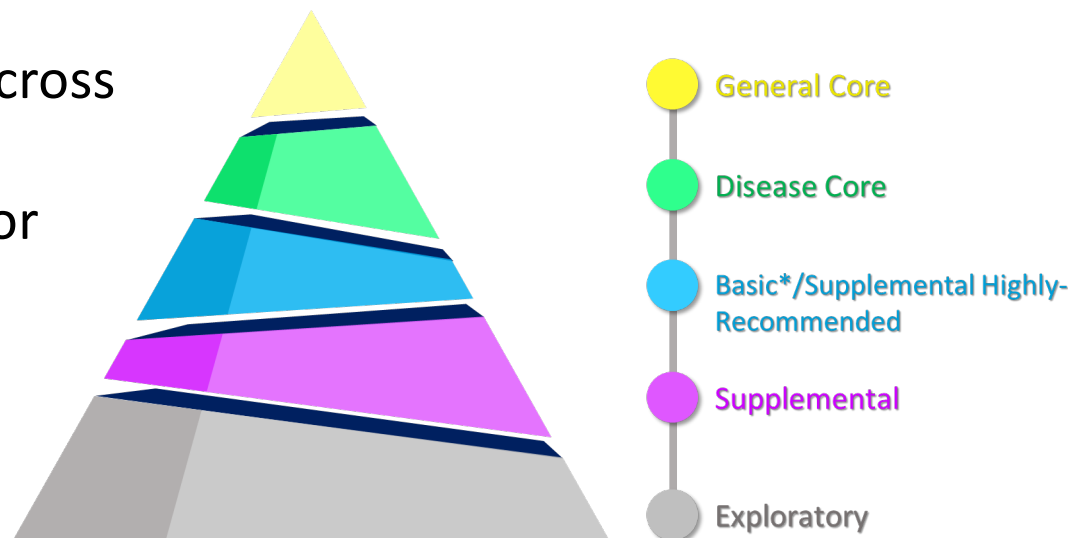
- Joseph T. Giacino, PhD
- Dave Mellick, PhD

Contractor:

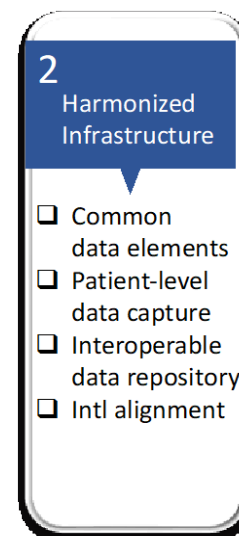
- Emmes

Purpose

- Facilitate comparison of findings across studies
- Establish stronger evidence base for treatment of TBI
- Identify overlap between TBI and psychological health disorders



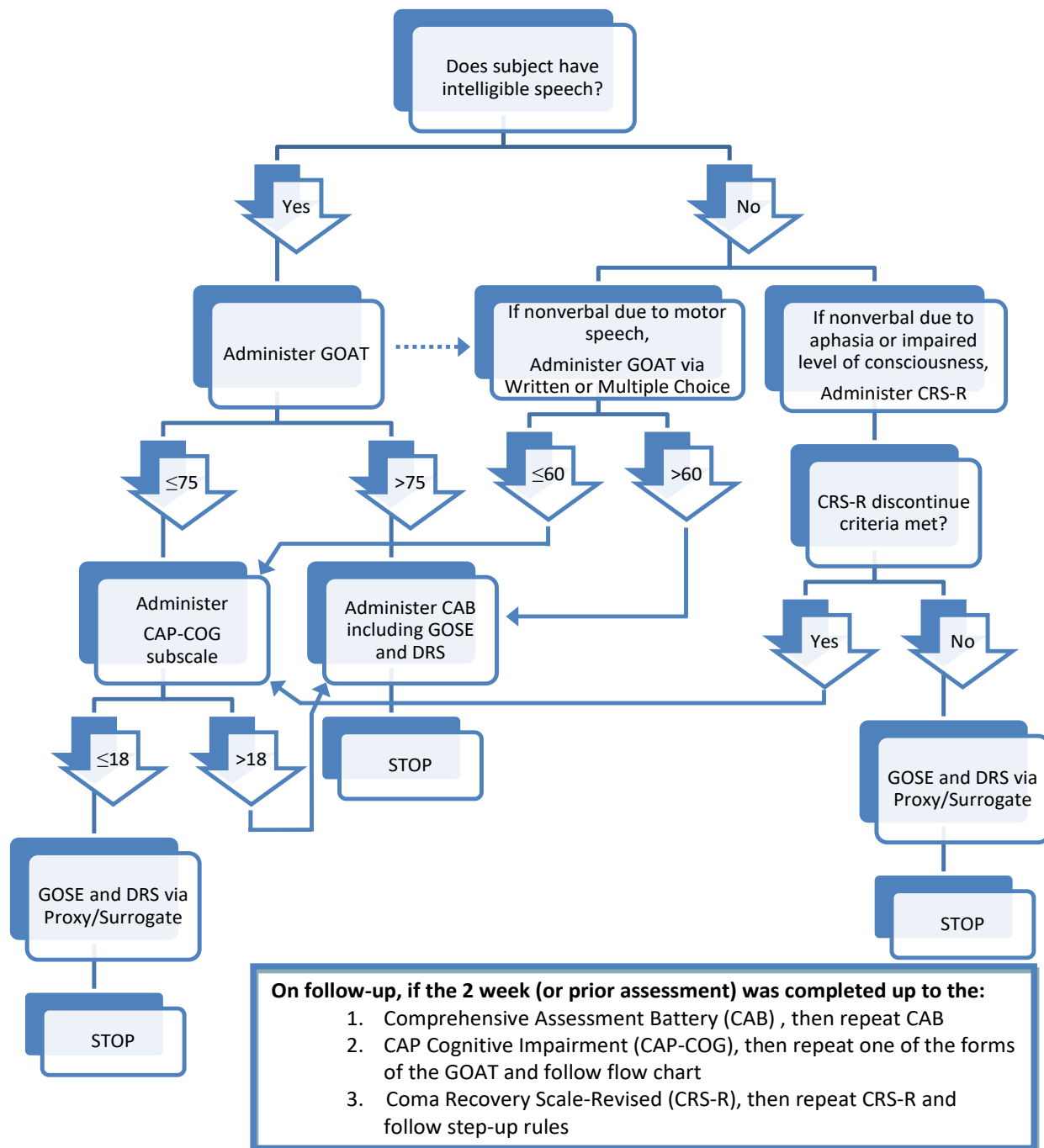
<http://www.commondataelements.ninds.nih.gov>



TRACK-TBI Flexible Outcome Assessment Battery (FAB)

Comprehensive Assessment Battery (CAB):

For subjects able to complete standardized neuropsychological assessment



Abbreviated Assessment Battery (AAB):

For subjects with DoC, confusion or aphasia

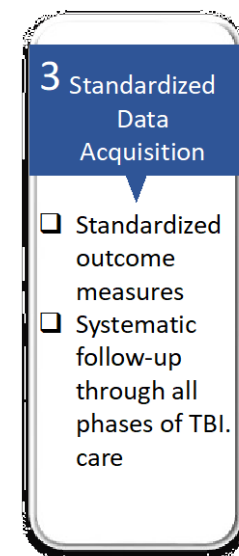
3 Standardized Data Acquisition

- ☐ Standardized outcome measures
- ☐ Systematic follow-up through all phases of TBI. care

TRACK-TBI Database

- 3749 participants enrolled (TBI: concussion to coma)
 - 300 controls (150 ortho trauma + 150 friend controls)
- > 3000 data fields per participant
- 3,220 standardized Adult MRIs (2w and 6m)
- 42,000 biospecimen samples (DNA, RNA, Plasma, Serum)
- 3,240 follow-ups between 2 and 8 years post-injury

<https://tracktbinet.ucsf.edu/>





TBI Endpoints Development

A collaborative for advancing diagnosis and treatment of TBI

Objectives:

- Establish a collaborative, multidisciplinary team to advance the identification and validation of ***clinical outcome assessment measures (COAs) and biomarkers*** for use as potential FDA-qualified drug development tools (DDTs)
- Initiate development of ***CDISC data standards*** for trials involving diagnosis and treatment of mTBI to modTBI.

TED Metadataset

STUDY	Mild/Mod TBI Subjects	Controls	Years	Study Type	COAs ¹ (number)	Biomarkers ² (number)	Clinical Trials.gov
TRACK-TBI Pilot	479	0	2010-2013	Civilian	10	4	NCT01565551
Army STARRS	750	>6000	2010-2014	Military	6	6	
CRC	761	240	1998-2014	Sports	16	2	
Mission Connect	102	72	2010-2014	Military	17	4	
CNRM	350	20	2010-2014	Civilian	5	5	NCT01132937
HTH-1	136	111	2007-2011	Sports	12	0	NCT00666666
COBRIT	652	0	2007-2011	Civilian	9	3	NCT00666666
UW	853	234	1981-2005	Civilian	3	1	NCT00730448

2 Harmonized Infrastructure

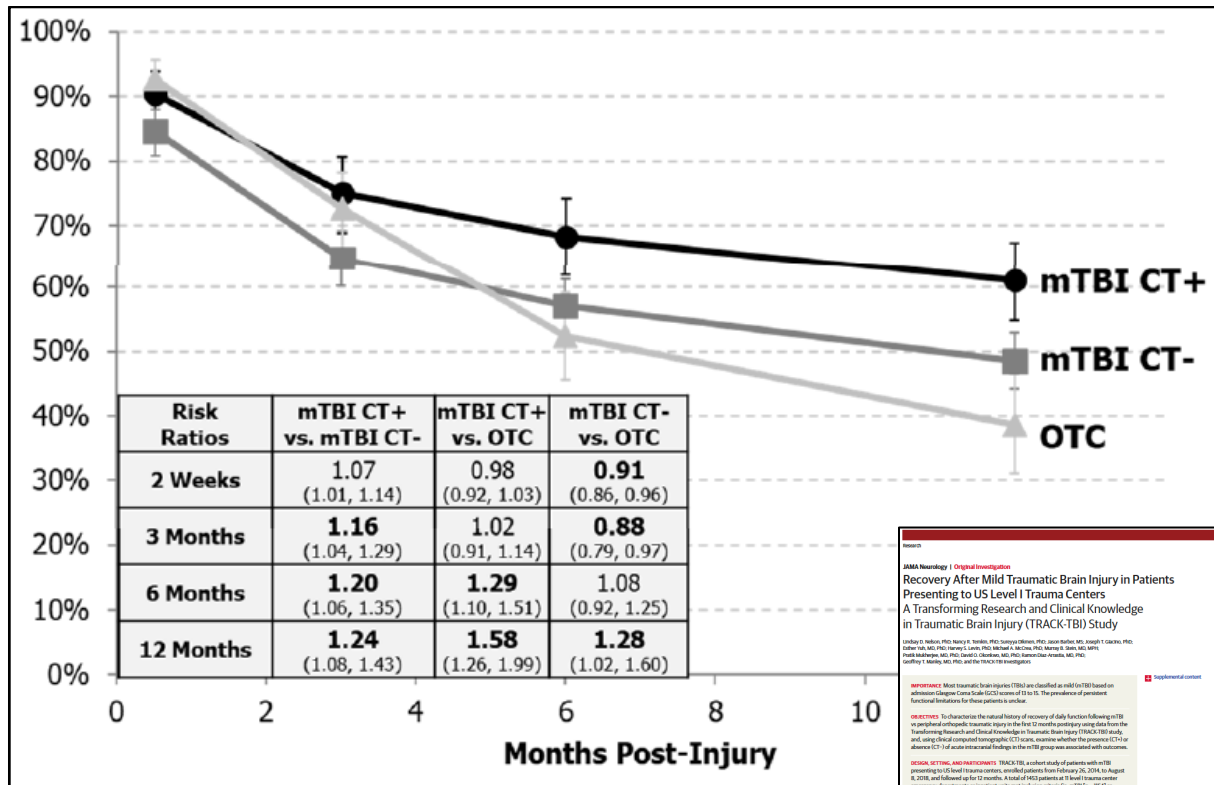
☐ Common data elements
 ☐ Patient-level data capture
 ☐ Interoperable data repository
 ☐ Intl alignment

3 Standardized Data Acquisition

☐ Standardized outcome measures
 ☐ Systematic follow-up through all phases of TBI care

TRACK-TBI Achievements: Natural history of recovery

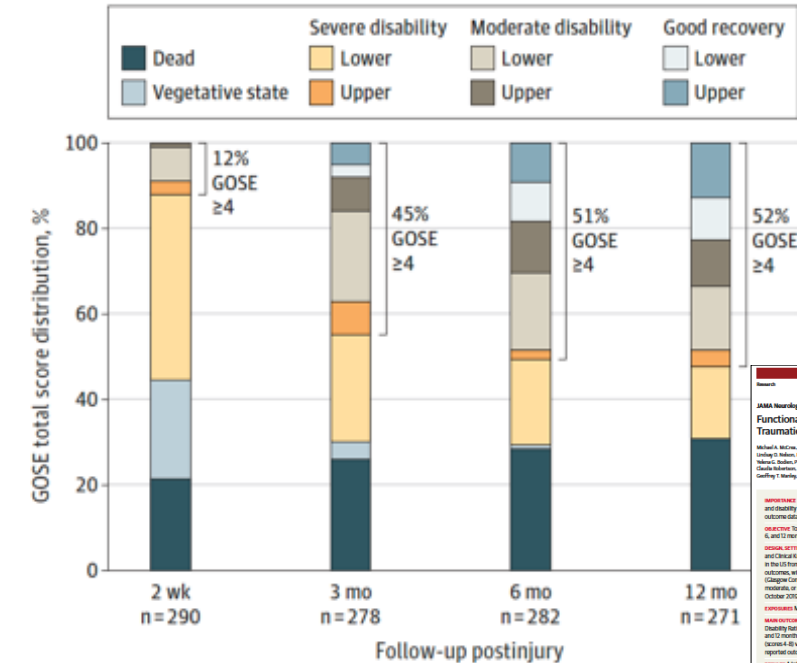
Trajectory of recovery across first 12 months after mTBI



GCS 13-15

Trajectory of recovery across first 12 months after sTBI

Figure 1. Glasgow Outcome Scale-Extended (GOSE) Total Score Distribution for Patients With Severe Traumatic Brain Injury at 2 Weeks and 3, 6, and 12 Months Postinjury



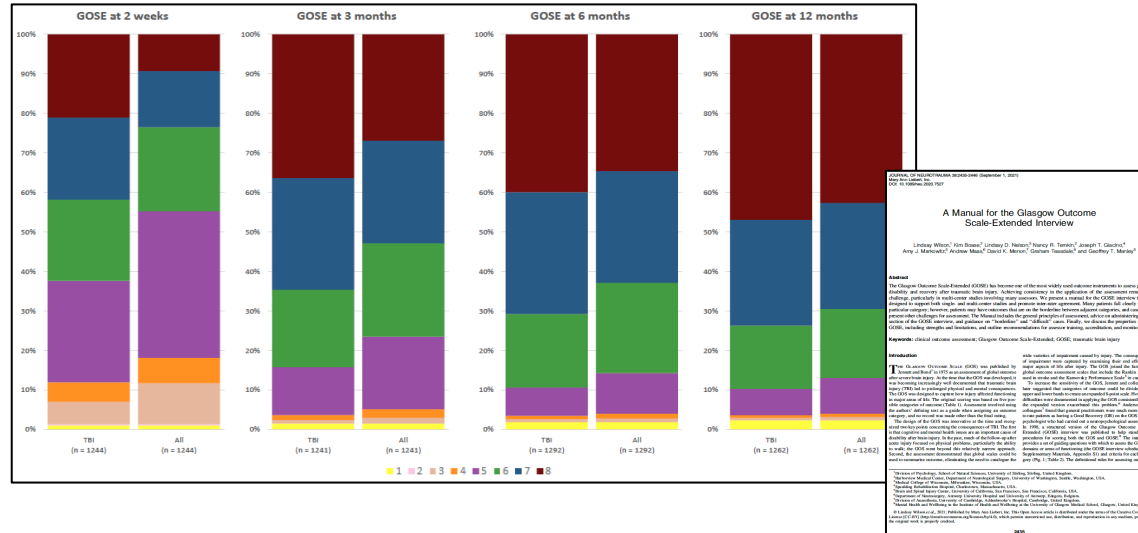
GCS 3-8

Abstract
Background: Recovery after mild traumatic brain injury (mTBI) is a complex process. The TRACK-TBI study is a prospective, longitudinal study of patients with mTBI, aiming to understand the natural history of recovery and the factors that influence outcomes.
Methods: The TRACK-TBI study is a prospective, longitudinal study of patients with mTBI, aiming to understand the natural history of recovery and the factors that influence outcomes.
Results: The TRACK-TBI study is a prospective, longitudinal study of patients with mTBI, aiming to understand the natural history of recovery and the factors that influence outcomes.
Conclusions: The TRACK-TBI study is a prospective, longitudinal study of patients with mTBI, aiming to understand the natural history of recovery and the factors that influence outcomes.

Abstract
Background: Moderate to severe traumatic brain injury (sTBI) is a major cause of death and disability in the US and worldwide. Few studies have evaluated prospective, longitudinal outcome data collection for sTBI to assess the natural history of recovery after mTBI.
Methods: The TRACK-TBI study is a prospective, longitudinal study of patients with sTBI, aiming to understand the natural history of recovery and the factors that influence outcomes.
Results: The TRACK-TBI study is a prospective, longitudinal study of patients with sTBI, aiming to understand the natural history of recovery and the factors that influence outcomes.
Conclusions: The TRACK-TBI study is a prospective, longitudinal study of patients with sTBI, aiming to understand the natural history of recovery and the factors that influence outcomes.

TRACK-TBI Achievements: Tools and Technologies

GOSE 2-Way Scoring (TBI-specific v. All cause)



EB-COP

Manual of Operating Procedures

An Evidence-Based Clinical Outcome Assessment Platform for Validation of TBI Assessment Measures (EB-COP)

Version 2

EB-COP Development Team
Joseph T. Giacino (PI), Michael McCrea, Meli
Ann Robbins, Thomas Getchius, Shannon Meril
Michael Bergin, Andrea Christoforou, Sal
Geoff Manley (Administrative)

Funded by the Department of Defense (Award # W



AMERICAN ACADEMY
NEUROLOGY

Clinical Data Interchange
Standards Consortium

Therapeutic Area Data Standards
User Guide for Traumatic Brain Injury
 Version 1.0 (Provisional)

Prepared by the
Traumatic Brain Injury Standards Team

Notes to Readers

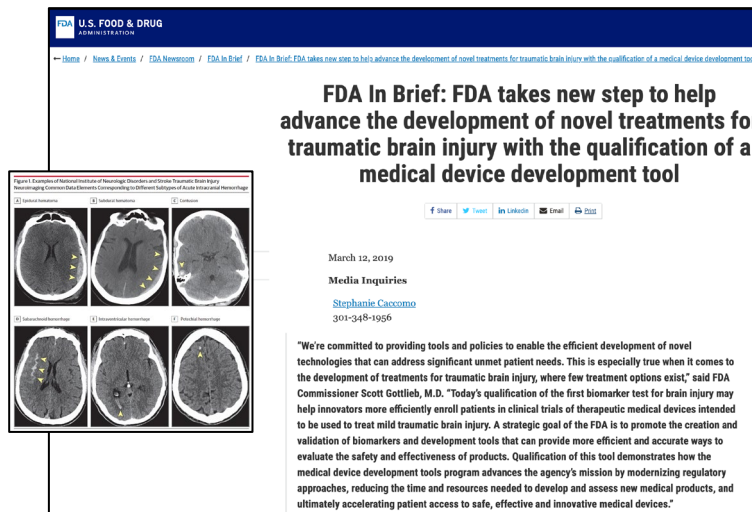
- This is version 1.0 of the Therapeutic Area Data Standards User Guide for Traumatic Brain Injury.
- This document is based on SDTM v1.4 and SDMIG v3.2, and on CDASH v1.1 and CDASHUG v1.0.

Revision History

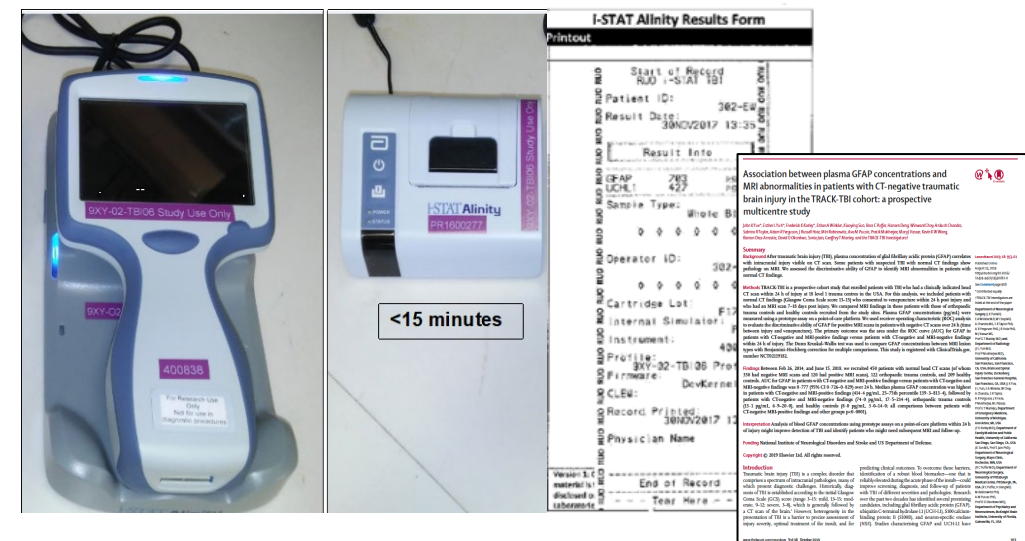
Date	Version	Summary of Changes
2015-12-02	1.0 Provisional	First release for provisional use
2015-07-13	1.0 Draft	Draft for public review

See [Appendix E](#) for Representations and Warranties, Limitations of Liability, and Disclaimers.

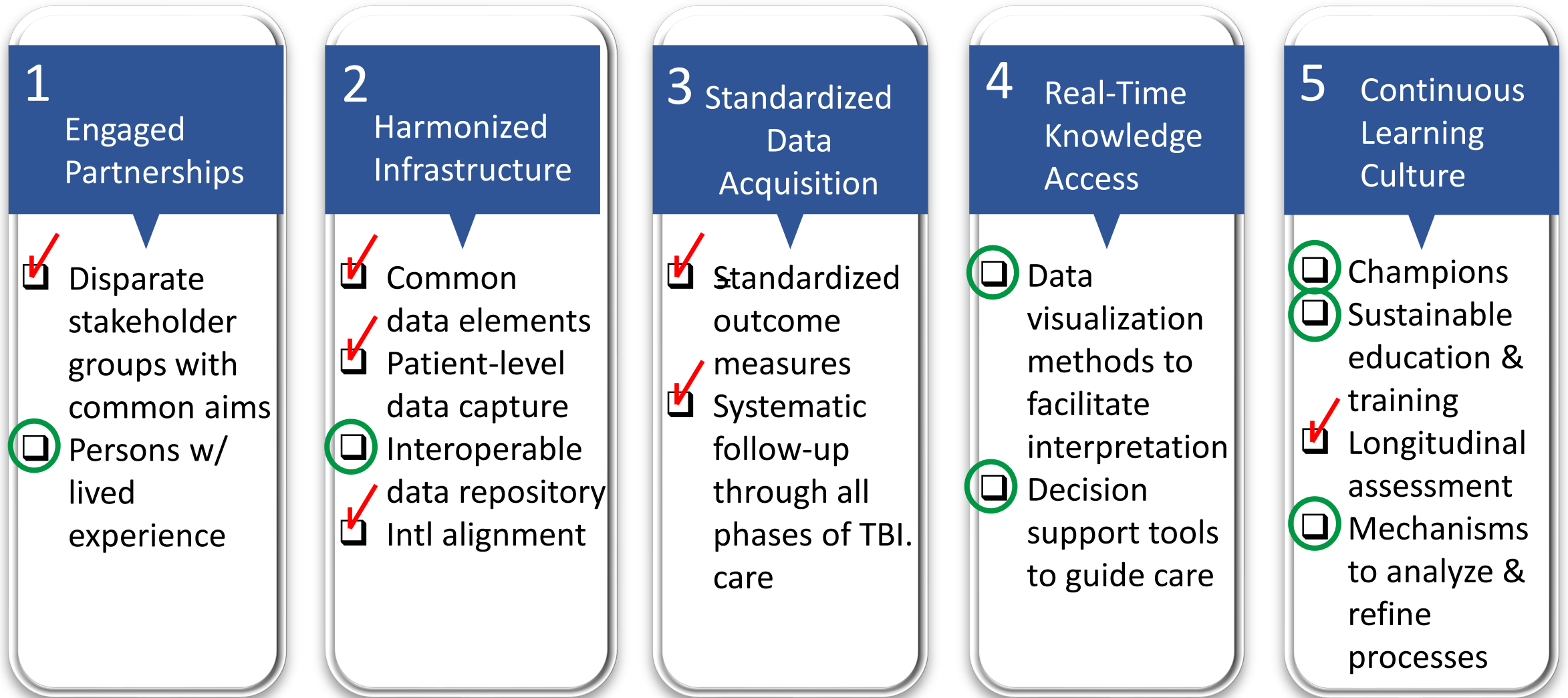
FDA-approved imaging biomarker for mTBI therapeutic trials



Abbott Labs iStat Alinity Point-of-Care device



TRACK-TBI LHS Scorecard



☐ = To-do

(IOM, 2007; NASEM, 2016; NASEM 2022)