NIH HEAL INITIATIVE

Group Discussions:

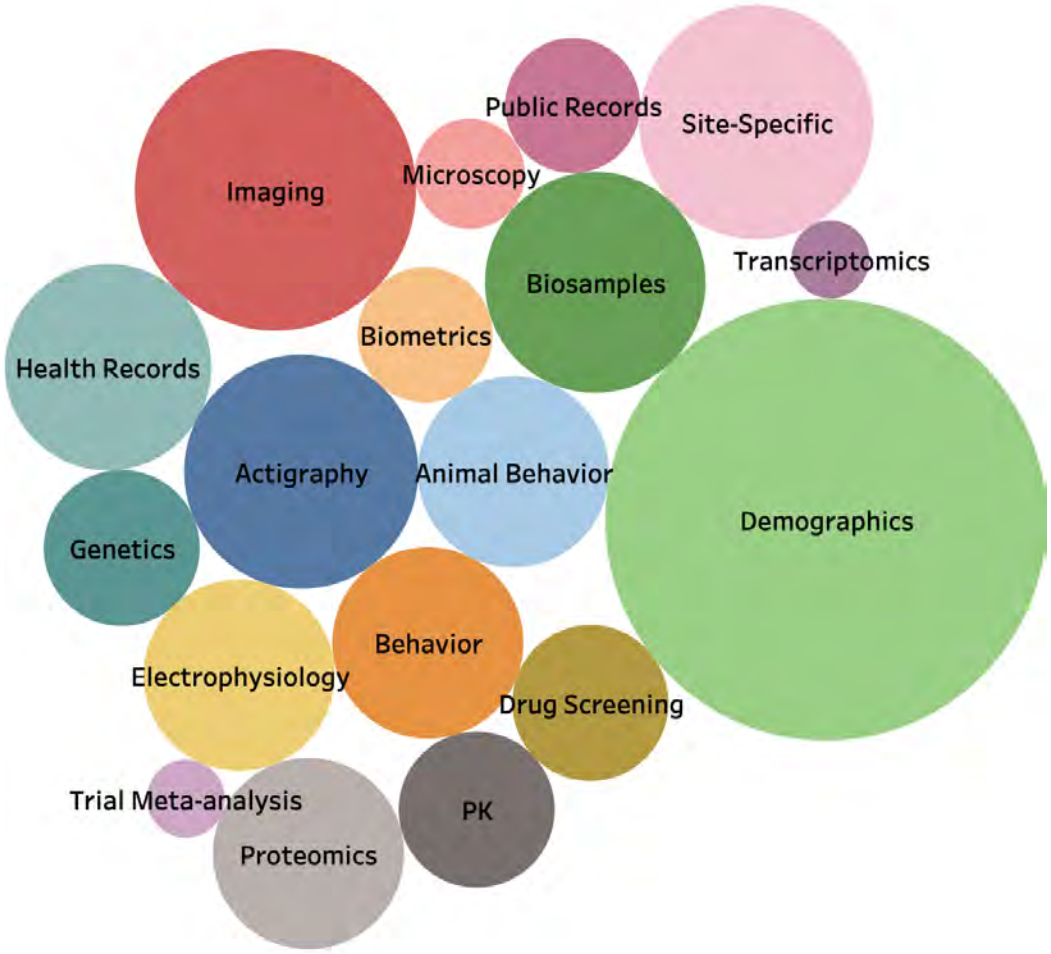
Data Sharing and Harmonization Across HEAL

NIH HEAL INITIATIVE

Focus Areas for Group Discussions

Therapeutics Development
Basic Science of Pain and Opioid Use Disorder
Clinical Trials: Phase 2 and Effectiveness Trials
Clinical Research: Implementation and Sustainability

All HEAL High-level Data Types



A HEAL Data Strategy assessment was conducted in 2019. Bubble size is proportional to number of assessment interviews mentioning an example of the data type.

BIOTEAM
Enabling Science

Example Therapeutics Development Programs

- Focusing Medication Development to Prevent and Treat OUD and Overdose
- Preclinical Screening Platform for Pain
- Development of Novel Drugs and Human Cell-Based Screening Platforms to Treat Pain and Opioid Use Disorder
- Optimizing Non-Addictive Therapies to Treat Pain
- Translating Discoveries into Effective Devices to Treat Pain
- Immunotherapies for Opioids to Prevent Relapse and Overdose
- Back Pain Consortium Research Program: Technology Research Sites

Therapeutics Development Data Types

Genetics	Human WGS	Human Microarray					
Proteomics	Human CNS Protein	Rodent CNS Protein	Primate CNS Protein				
Transcriptomics	Human CNS RNA						
Pharmacokinetics	Drug Metabolites	Intermediary Metabolites					
Animal behavior	Tail Flick	Thermal Tolerance	Electrical Tolerance	Biomechanical Reaction	Touch Reaction	Sleep States	Hormones and Factors
Drug Candidate Assays	HTS	Secondary Screens	X-Ray Crystallography				
Size Key	1 Gigabyte or more	10s to 100s of Megabytes	Less than 10 Megabytes				

A HEAL Data Strategy assessment was conducted in 2019. A small number of Interviewees discussed the data types they would expect in their programs.

Example Basic Science of Pain and Opioid Use Disorder Programs

- Sleep Dysfunction as a Core Feature of Opioid Use Disorder and Recovery
- Discovery and Validation of Biomarkers, Endpoints, and Signatures for Pain Conditions
- Discovery and Validation of Novel Targets for Safe and Effective Treatment of Pain
- Sleep Dysfunction as a Core Feature of Opioid Use Disorder and Recovery
- Back Pain Consortium Research Program: Technology Research Sites

Basic Science of Pain and Opioid Use Disorder Programs Data Types

Electrophysiology	Polysomnography (PSG)	EEG	EKG	MEG	Patch Clamp (DRG)	Patch Clamp (Biopsy)	
Behavior	Video Recordings	Audio Recordings					
Biosamples	Sample IR Spectroscopy						
Microscopy	Confocal Microscopy	Light Microscopy					
Actigraphy	Steps	Geolocation (GPS)	Sleep States	Heart Rate	Skin Moisture		
Imaging	fMRI / MRI	PET	Ultrasound	CT	X-Ray		
Genetics	Human WGS	Human Microarray					
Proteomics	Human CNS Protein	Rodent CNS Protein	Primate CNS Protein				
Transcriptomics	Human CNS RNA						
Pharmacokinetics	Drug Metabolites	Intermediary Metabolites					
Animal behavior	Tail Flick	Thermal Tolerance	Electrical Tolerance	Biomechanical Reaction	Touch Reaction	Sleep States	Hormones and Factors
Size Key	1 Gigabyte or more	10s to 100s of Megabytes	Less than 10 Megabytes				

A HEAL Data Strategy assessment was conducted in 2019. A small number of Interviewees discussed the data types they would expect in their programs.

Example Clinical Trial - Phase 2 and Effectiveness Trials Programs

- Early Phase Pain Investigation Clinical Network (EPPIC-Net)
- Back Pain Consortium Research Program: phase 2 clinical trials, Data Integration, Algorithm Development and Operations Management, Mechanistic Research Centers
- Pain Management Effectiveness Research Network
- Integrated Approach to Pain and Opioid Use in Hemodialysis Patients
- Prevention of Progression to Moderate or Severe Opioid Use Disorder
- Optimizing the Duration, Retention, and Discontinuation of Medication Treatment for Opioid Use Disorder
- Enhancing the National Drug Abuse Treatment Clinical Trials Network to Address Opioids
- Advancing Clinical Trials in Neonatal Opioid Withdrawal (ACT NOW)
- Behavioral Research to Improve Medication-Based Treatment

Clinical Trial - Phase 2 and Effectiveness Trials Data Types

Demographics	Ethnicity	Location	Gender	Disease States	
Health Records	Electronic Medical Records				
Biometrics	Height	Weight	Hip Circumference		
Clinical Studies	Trial Meta-analysis				
Electrophysiology	Polysomnography (PSG)	EEG	EKG	MEG	
Behavior	Video Recordings	Audio Recordings	Self-reported Pain	Self-reported Mood	Eye Tracking (Visual Attention)
Biosamples	Blood Metabolites	Urinalysis	Microbiome (Feces)	Chemical Clearing (Feces)	Sample IR Spectroscopy
Microscopy	Confocal Microscopy	Light Microscopy			
Actigraphy	Steps	Geolocation (GPS)	Sleep States	Heart Rate	Skin Moisture
Imaging	fMRI / MRI	PET	Ultrasound	CT	X-Ray
Genetics	Human WGS	Human Microarray			
Proteomics	Human CNS Protein	Rodent CNS Protein	Primate CNS Protein		
Transcriptomics	Human CNS RNA				
Pharmacokinetics	Drug Metabolites	Intermediary Metabolites			
Size Key	1 Gigabyte or more	10s to 100s of Megabytes	Less than 10 Megabytes		

A HEAL Data Strategy assessment was conducted in 2019. A small number of Interviewees discussed the data types they would expect in their programs.

Example Clinical Research: Implementation and Sustainability Programs

- HBCD (HEALthy Brain and Child Development)
- Pragmatic and Implementation Studies for the Management of Pain to Reduce Opioid Prescribing (PRISM)
- Optimizing Collaborative Care for People with Opioid Use Disorder and Mental Health Conditions
- Preventing At-Risk Adolescents Transitioning into Adulthood from Developing Opioid Use Disorder
- Justice Community Opioid Innovation Network
- HEALing Communities Study
- Behavioral Research to Improve Medication-Based Treatment

Clinical Research: Implementation and Sustainability Programs Data Types

Demographics	Ethnicity	Location	Gender	Disease States	
Site-Specific	OUD Incidence	OUD Deaths	Census Data	Naloxone Distribution	MAT Data
Health Records	Electronic Medical Records	EDIE * Records	MAT Data		
Public Records	Justice Setting Records	Public Health Records	Social Service Records		
Biometrics	Height	Weight	Hip Circumference		
Clinical Studies	Trial Meta-analysis				
Electrophysiology	Polysomnography (PSG)	EEG	EKG	MEG	
Behavior	Self-reported Pain	Self-reported Mood			
Biosamples	Blood Metabolites	Urinalysis	Microbiome (Feces)	Chemical Clearing (Feces)	Sample IR Spectroscopy
Actigraphy	Steps	Geolocation (GPS)	Sleep States	Heart Rate	Skin Moisture
Imaging	fMRI / MRI	PET	Ultrasound	CT	X-Ray
Genetics	Human WGS	Human Microarray			
Proteomics	Human CNS Protein				
Transcriptomics	Human CNS RNA				
Pharmacokinetics	Drug Metabolites	Intermediary Metabolites			
		* Emergency Department Information Exchange			
Size Key	1 Gigabyte or more	10s to 100s of Megabytes	Less than 10 Megabytes		

A HEAL Data Strategy assessment was conducted in 2019. A small number of Interviewees discussed the data types they would expect in their programs.

HEAL Public Access and Data Sharing Policy

- Electronic copies of publications will be deposited within 4 weeks of acceptance
- Publications will be Published under the Creative Commons Generic License
- Publications will be made publicly available immediately without embargo
- Underlying Primary Data for the Publications will be made broadly available
- Sharing of Underlying Primary Data must be responsive to protecting confidential and proprietary data and is consistent with applicable laws and regulations
- See https://heal.nih.gov/about/public-access-data

HEAL data harmonization and sharing

- To achieve our bold goals some preparatory work will be needed
  - Standardization
  - Uploading and sharing
  - Harmonization
- We also have to consider how research data can be shared and made FAIR
  - Through a HEAL Cloud platform
  - Through HEAL data management services

Goals for Small Group Sessions

- Introduce goals and opportunities of HEAL data harmonization and sharing
- Share NIH's vision and plans to develop a data management infrastructure
- Gather feedback on what resources and communication strategies would benefit investigators
- Gather information on data needs of the investigator community
- Hear about the investigators' concerns
- Gain insight from investigators' plans and best practices

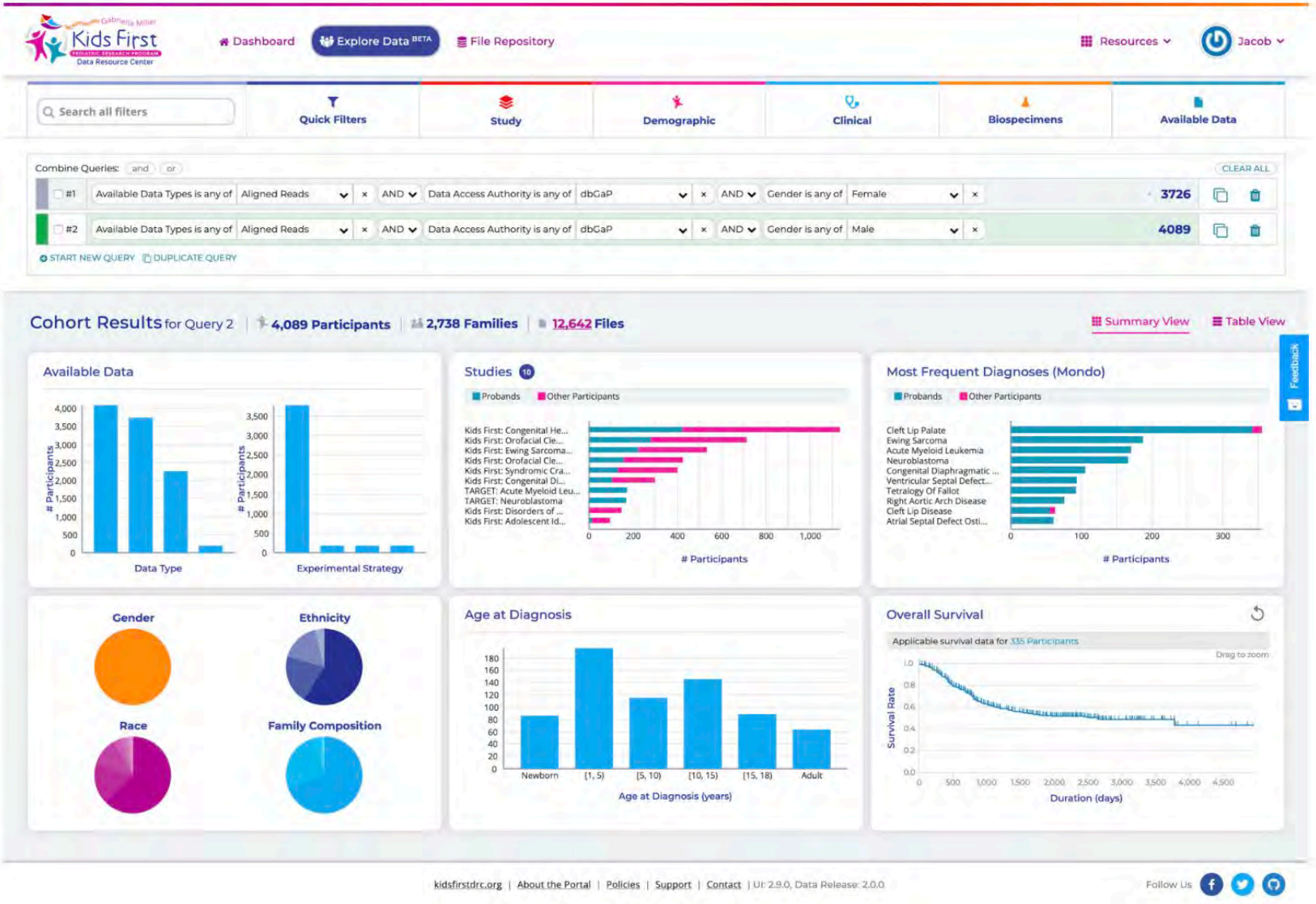
HEAL Data Harmonization

- Many programs have specific data coordinating centers awarded and in place … and many programs do not.
- Some are actively working on strategies, some are more likely to let look to HEAL for direction.
- HEAL is planning to support scientific teams and PIs through additional data management and harmonization services.
- NIH plans to support investigators in being compliant with letter and spirit of the party

Enabling the HEAL Cloud Platform

- NIH is a world-leader in awarding and build Cloud research platforms.
- At this time HEAL leads the platform design and build, while awardees focus on research
- NIH has established STRIDES to facilitate Cloud storage and compute – essential for data science goals
- NIH will make STRIDES and other resources available to HEAL awardees so that data can be placed in the Cloud

The Cloud Platform and Your Research



The Cloud Platform and Your Research

- The platform will
  - enable synthetic cohorts
  - discover rare signals in large data sets, and co-occurring conditions
  - enable study across previously unconnected domains.
  - enable you to take advantage of cutting edge tools easily.
  - give you access to unique data sets.
  - have archival and active storage
  - simplify data submission
  - be fully search-able
  - be secure, and easy-to-access

www.heal.nih.gov