The NIH Distributed Research Network
New Functionality and Future Potential

Millions of people. Strong collaborations. Privacy first.

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The goal

Facilitate multi-site research collaborations between investigators and data partners by creating secure networking capabilities and analysis tools for electronic health data
Vision for the Network:
Many types of organizations and data

NIH Distributed Research Network Secure Portal

- Health Plan 1
- Health Plan 2
- CTSA 1
- CTSA 2
- Registry 1
- Registry 2
- Research Dataset 1
- Research Dataset 2
Multiple data sources
A distributed network links data sources

FDA Mini-Sentinel

Health Plan 1  Health Plan 4  Health Plan 7
Health Plan 2  Health Plan 5  Health Plan 8
Health Plan 3  Health Plan 6  Health Plan 9

Hospital 1  Hospital 4  Outpatient clinic 1
Hospital 2  Hospital 5  Outpatient clinic 2
Hospital 3  Hospital 6  Outpatient clinic 3
Outpatient clinic 4  Outpatient clinic 5  Outpatient clinic 6
Multiple networks share infrastructure

- Each organization can participate in multiple networks
- Each network controls its governance and coordination
- Networks share infrastructure, data curation, analytics, lessons, security, software development
Not the goal

We will **not** create a new stand-alone network with its own research agenda or content experts

Investigators will **not** have access to data without data partners’ active engagement
Year 1 progress

• Created and tested a secure network with distributed querying capabilities
• Identified initial data partners
• Established draft governance document
• Laid groundwork for querying i2b2 data repositories
Current partners

• Aetna
• Group Health Research Institute
• Harvard Pilgrim Health Care
• HealthCore
• Humana
• Optum

Approximately 40 million current members
Current data and functionality

- Routinely updated and quality-checked data
- Over 90 million covered lives
  - Complete data capture for defined intervals
  - Inpatient and outpatient encounters, diagnoses, procedures
  - Outpatient pharmacy dispensings
  - Demographics
- Mini-Sentinel common data model
- Functionality includes
  - Simple queries of pre-compiled frequencies
  - Standardized queries of person-level data
Distributed data / distributed analysis

- Data partners keep and analyze their own data
- Standardize the data using a common data model
- Distribute code to partners for local execution
- Provide results, not data, to requestor
- All activities audited and secure
Use cases

✓ Assess disease burden/outcomes
✓ Pragmatic clinical trial design
✓ Single study private network
  • Pragmatic clinical trial follow up
  • Reuse of research data
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NIH question

What is the rate of fractures among new bisphosphonate users with a prior diagnosis of osteoporosis?
Query of pre-compiled counts

• Drugs
  • Alendronate sodium
  • Pamidronate disodium
  • Zoledronic acid, Zometa
  • Zoledronic acid, Reclast

• ICD9-CM codes for fracture
  • 805xx (vertebral w/o spinal cord injury)
  • 806xx (vertebral with spinal cord injury)
  • 820xx (neck of femur)
Alendronate users by year and age group*

* Incident users based on a 90-day wash-out period

~90,000 in 2012
Pamidronate disodium users by year and age group*

~1,400 in 2012

*Prevalent users based on HCPCS J2430
Zolendronic acid (Reclast) users by year and age group*

*Prevalent users based on HCPCS J3488

~20,000 in 2012
Zolendronic acid (Zometa) users by year and age group*

*Prevalent users based on HCPCS J3487

~11,000 in 2012
Hip fracture*

~30,000 in 2012

*Prevalence

~30,000 in 2012
Vertebral fracture w/o injury to spinal cord* 

~22,000 in 2012

*Prevalence
Vertebral fracture with injury to spinal cord*

*Prevalence

~2,900 in 2012

*Prevalence
Standardized query of patient-level data

Validated SAS programs with flexible inputs for exposure, outcome, and other settings
Key specifications of standardized query

• Define cohort
• Define incident user
• Define incident events
• Query period
• Age range
• Continuous enrollment gap
• Coverage (medical and drug) requirements
Specifications for bisphosphonate request

- **Cohort:** Members 40+ years old with an osteoporosis diagnosis and no fractures in the 365 days before new use
- **Incident exposure:** New users of ANY of the 4 bisphosphonates based on a 365 day wash-out period
- **At risk period:** 365 days after incident exposure
- **Incident outcome:** Observed fracture (hip, vertebral, non-hip/non-vertebral) in any care setting among new users
- **Query period:** January 1, 2008 - December 31, 2012
- **Age groups:** 40-54, 55-64, 65+ years
- **Continuous enrollment gap:** 45 days
Incident users

![Bar chart showing the number of incident users for different drugs: Alendronate (131,056), Pamidronate (365), Reclast (36,593), and Zometa (2,919).]
Fractures among incident users
Fracture rate among incident users (per 100,000 days at risk)*

*Unadjusted
Caveats

• Data intended as an example of network capability
• Standard limitations of electronic health data
  • Use of diagnosis codes to identify osteoporosis and fractures
  • Codes not validated
  • Treatment indication not available
  • Privately insured population with stable enrollment
• Bisphosphonate usage is complex
  • Different routes of administration
  • Different indications
  • Different patterns of use
• Rates not adjusted
Clinical trials and complex observational studies

- Standardized programs inform development of full study protocols
- NIH DRN can support any analysis
- NIH DRN facilitates creation and use of pooled analytic datasets
Use cases

✓ Assess disease burden/outcomes
✓ Pragmatic clinical trial design
✓ **Single study private network**
  • Pragmatic clinical trial follow up
  • Reuse of research data
The NIH Collaboratory’s LIRE project

• Creating a network among the LIRE sites and its coordinating center
  • U Washington (Coordinating center)
  • Group Health Cooperative
  • Kaiser Permanente of Northern Cal.
  • Henry Ford Health System
  • Mayo Clinic
• Coordinating center can distribute programs to sites securely
• Sites can return results securely
Next steps

- Add most Kaiser Permanente and HMO Research Network plans
- Develop new querying and networking functionality
- Potential to expand to other data models
  - i2b2 networks
  - ESP networks
  - CTSAs
  - Registries
  - Others
The DRN is ready for NIH to use

- Assess disease burden/outcomes
- Pragmatic clinical trial design
- Single study private network
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- Reuse of research data
Thank You

For more information
- nihcollaboratory.org/Pages/distributed-research-network.aspx
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Prior Grand Rounds
June 28, 2013

March 15, 2013