NIH Collaboratory

Health Care Systems Research Collaboratory

The NIH Distributed Research Network
New Functionality and Future Potential

Millions of people. Strong collaborations. Privacy first.

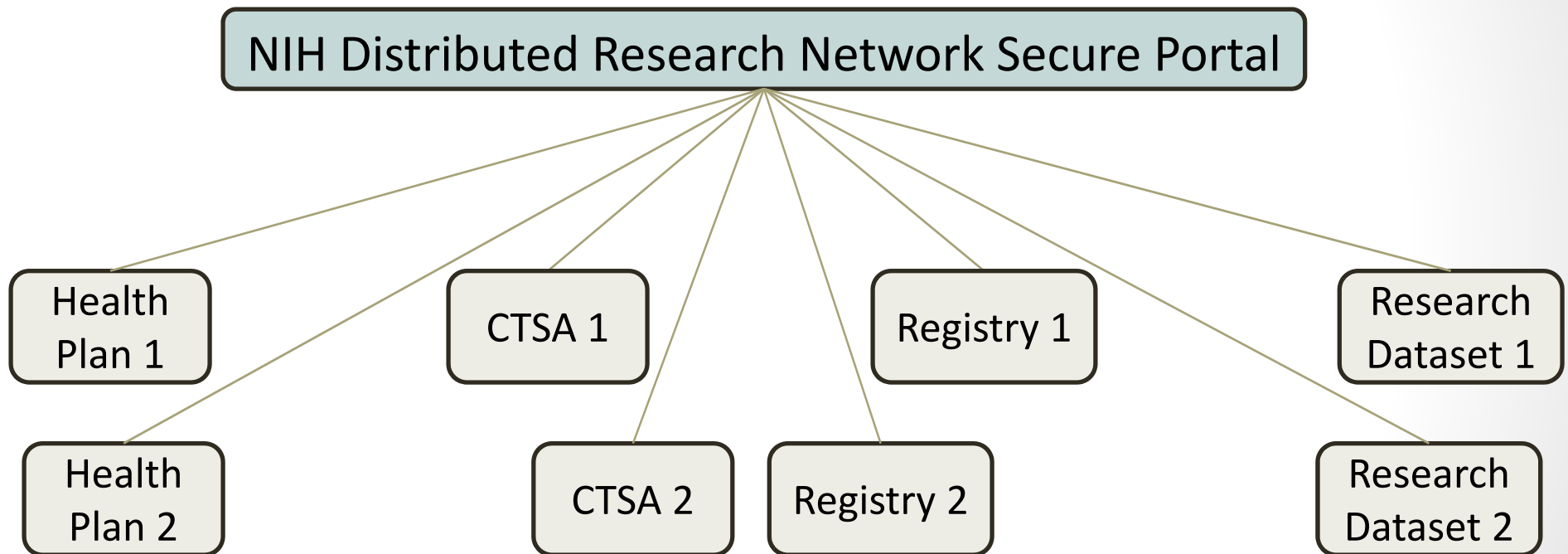Jeffrey Brown, PhD for the NIH Health Care Systems Collaboratory EHR Core

Harvard Pilgrim Health Care Institute and Harvard Medical School
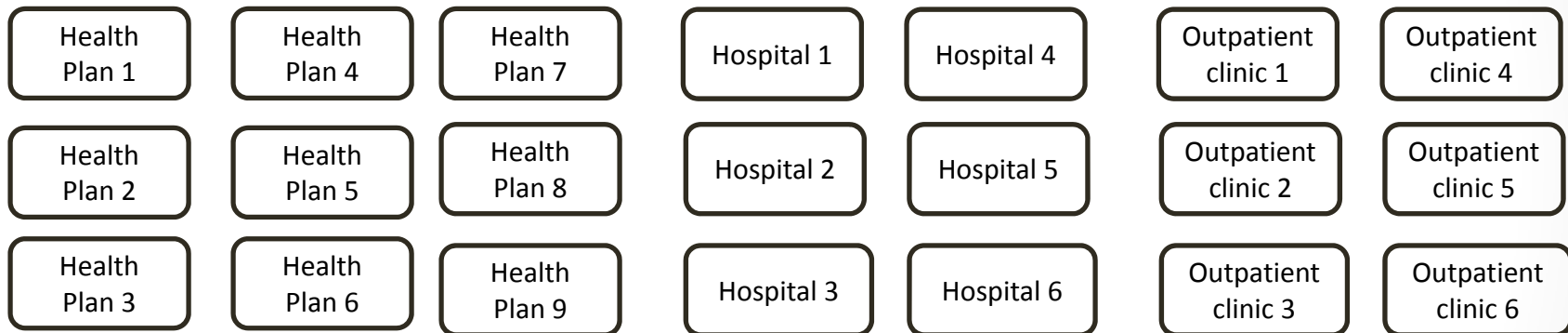
September 13, 2013

The goal

Facilitate multi-site research collaborations between investigators and data partners by creating secure networking capabilities and analysis tools for electronic health data

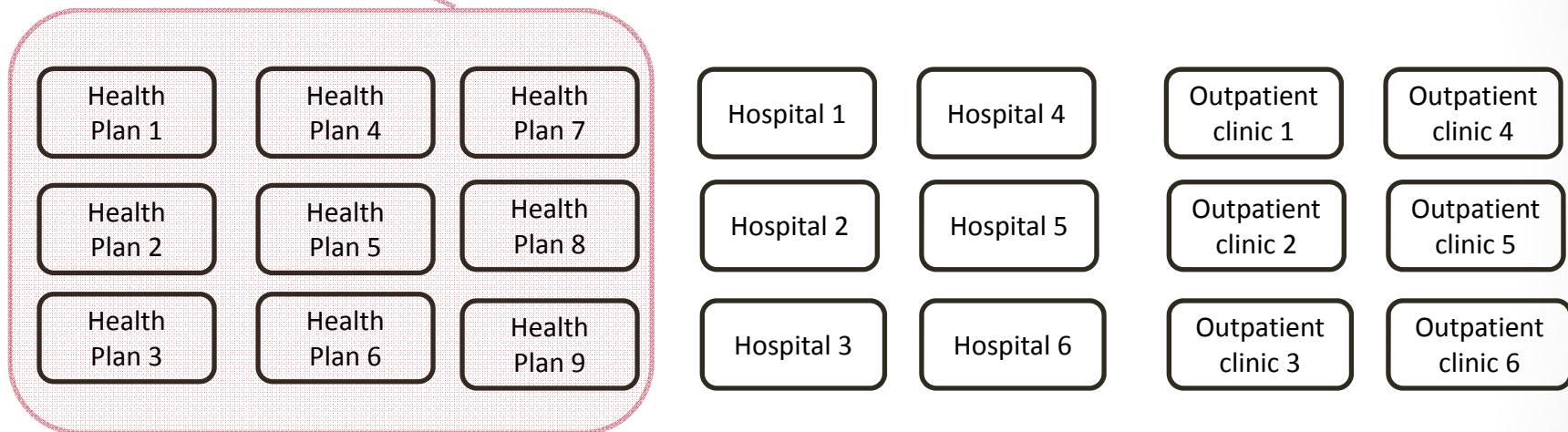# Vision for the Network:
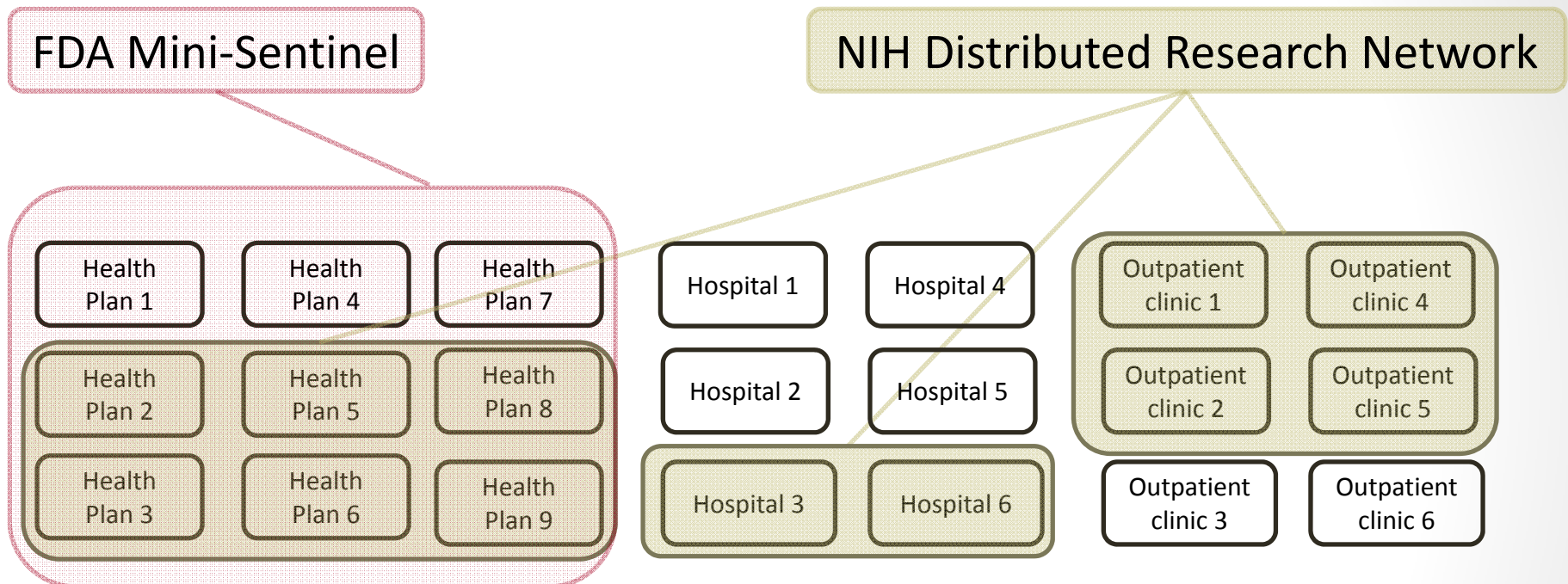# Many types of organizations and data

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

Health Plan 1	Health Plan 4	Health Plan 7	Hospital 1	Hospital 4	Outpatient clinic 1	Outpatient clinic 4
Health Plan 2	Health Plan 5	Health Plan 8	Hospital 2	Hospital 5	Outpatient clinic 2	Outpatient clinic 5
Health Plan 3	Health Plan 6	Health Plan 9	Hospital 3	Hospital 6	Outpatient clinic 3	Outpatient clinic 6

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	Outpatient clinic 4
Hospital 2	Hospital 5	Outpatient clinic 2	Outpatient clinic 5
Hospital 3	Hospital 6	Outpatient clinic 3	Outpatient clinic 6

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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

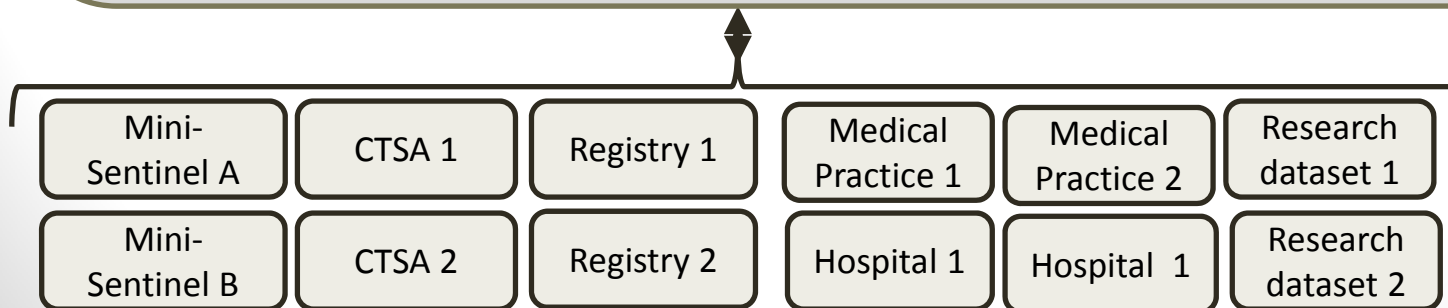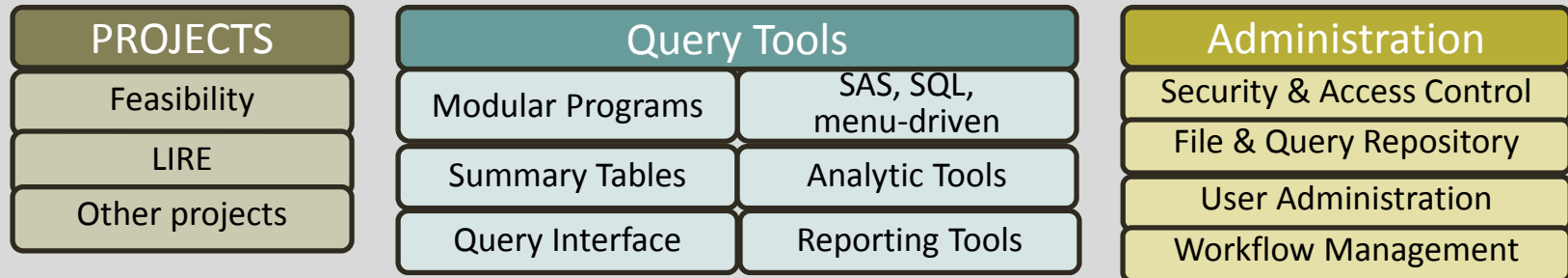- Laid groundwork for querying i2b2 data repositories

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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 <u>keep and analyze</u> their own data

- Standardize the data using a <u>common data model</u>

- <u>Distribute code</u> to partners for local execution

- <u>Provide results</u>, not data, to requestor

- All activities <u>audited</u> and <u>secure</u>

Use cases

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

Use cases

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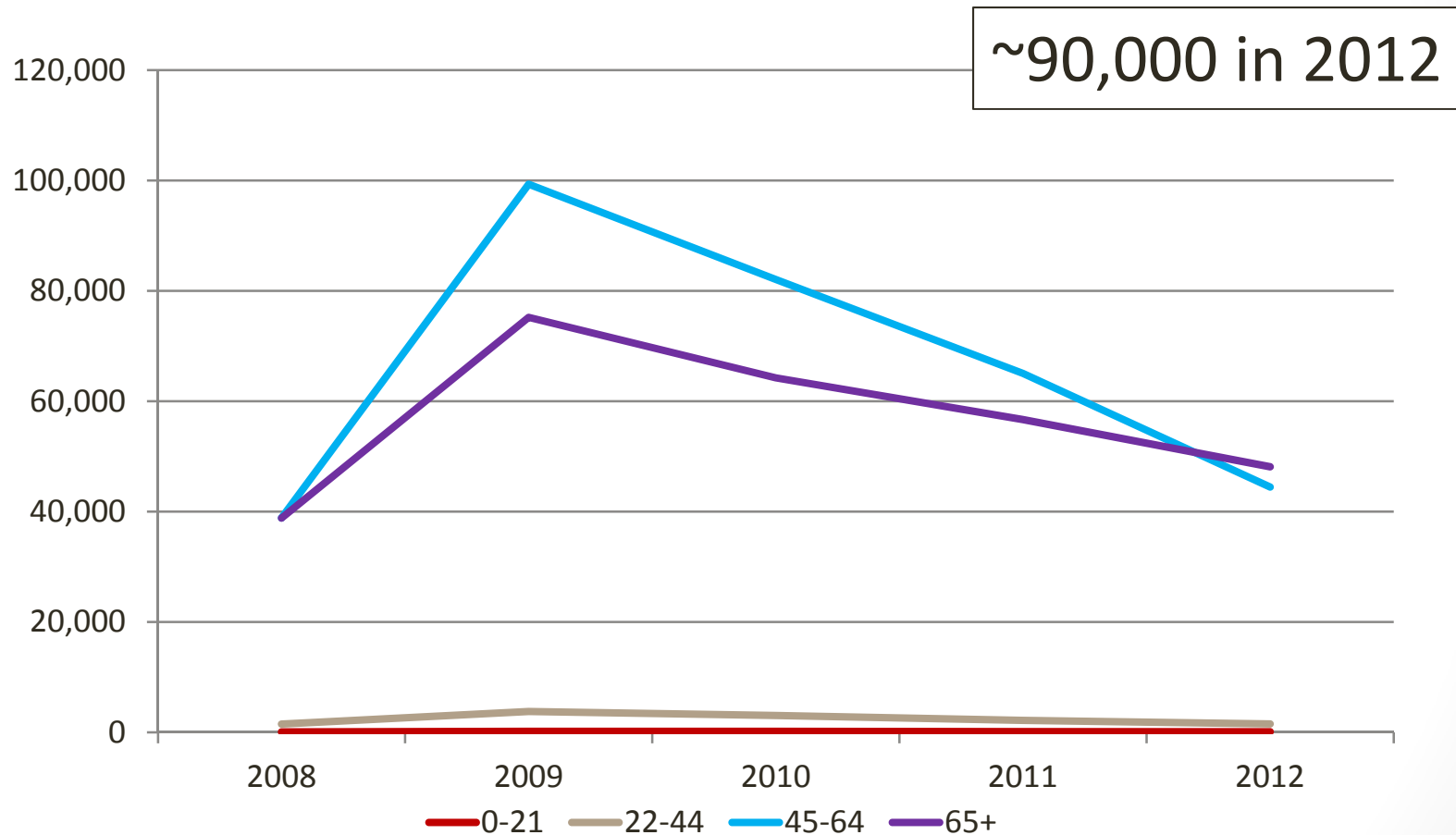- Pragmatic clinical trial follow up
- Reuse of research data

NIH question

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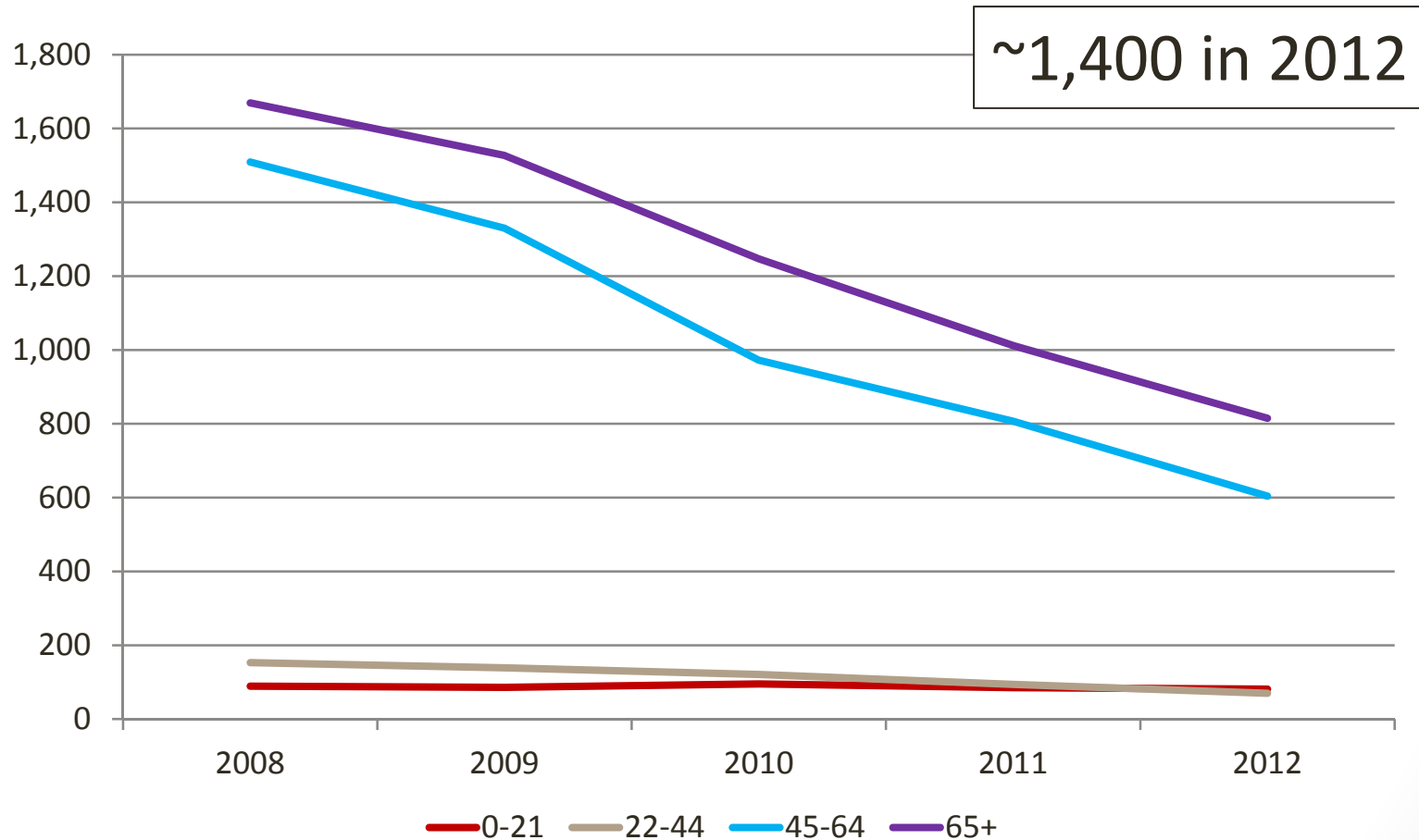
Query of pre-compiled counts

- 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)
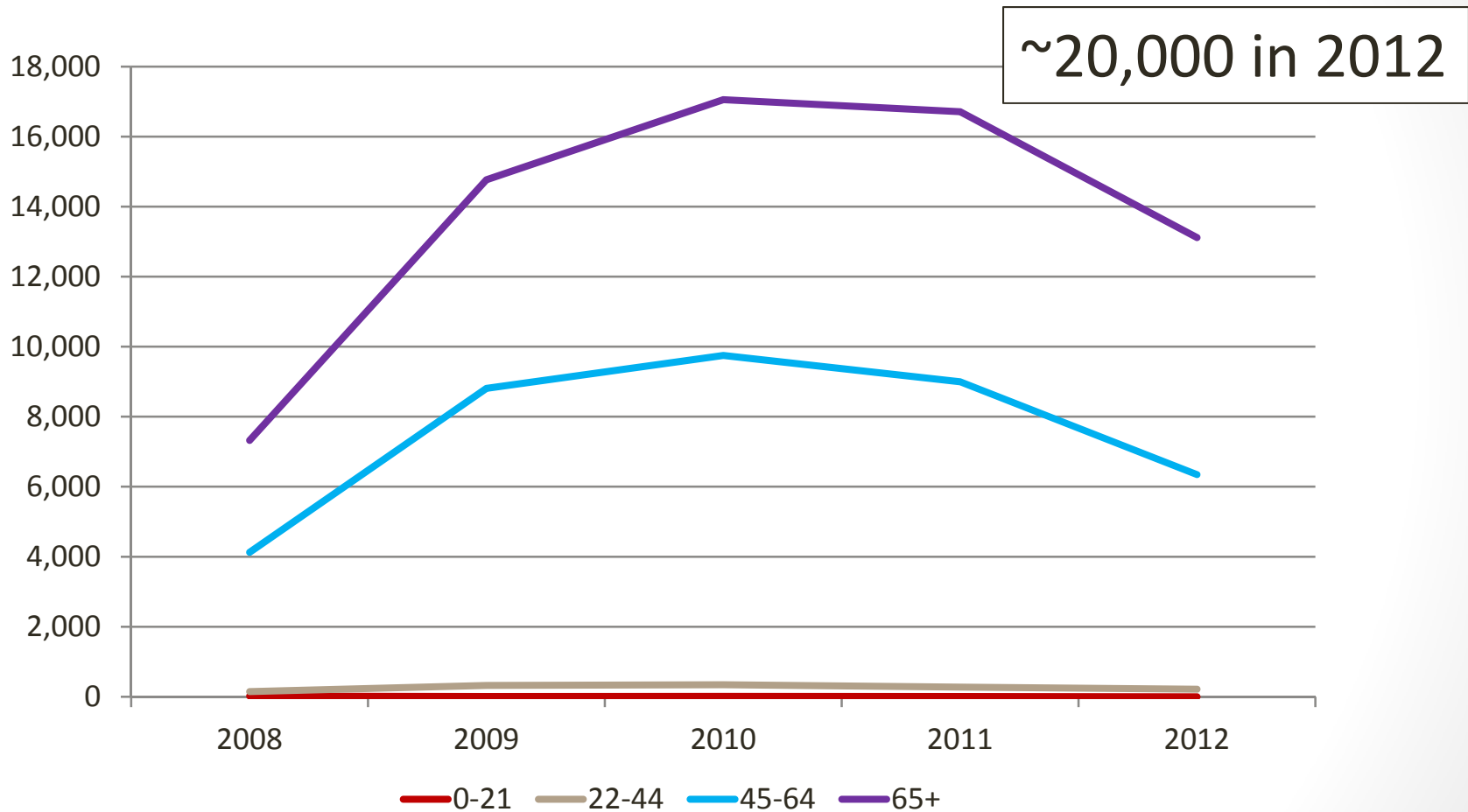
Alendronate users
by year and age group*

~90,000 in 2012

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

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Pamidronate disodium users by year and age group*

~1,400 in 2012

Legend: 0-21, 22-44, 45-64, 65+

*Prevalent users based on HCPCS J2430

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Zolendronic acid (Reclast) users by year and age group*

~20,000 in 2012

*Prevalent users based on HCPCS J3488

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Zolendronic acid (Zometa) users by year and age group*

~11,000 in 2012

*Prevalent users based on HCPCS J3487

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Hip fracture*

~30,000 in 2012

*Prevalence

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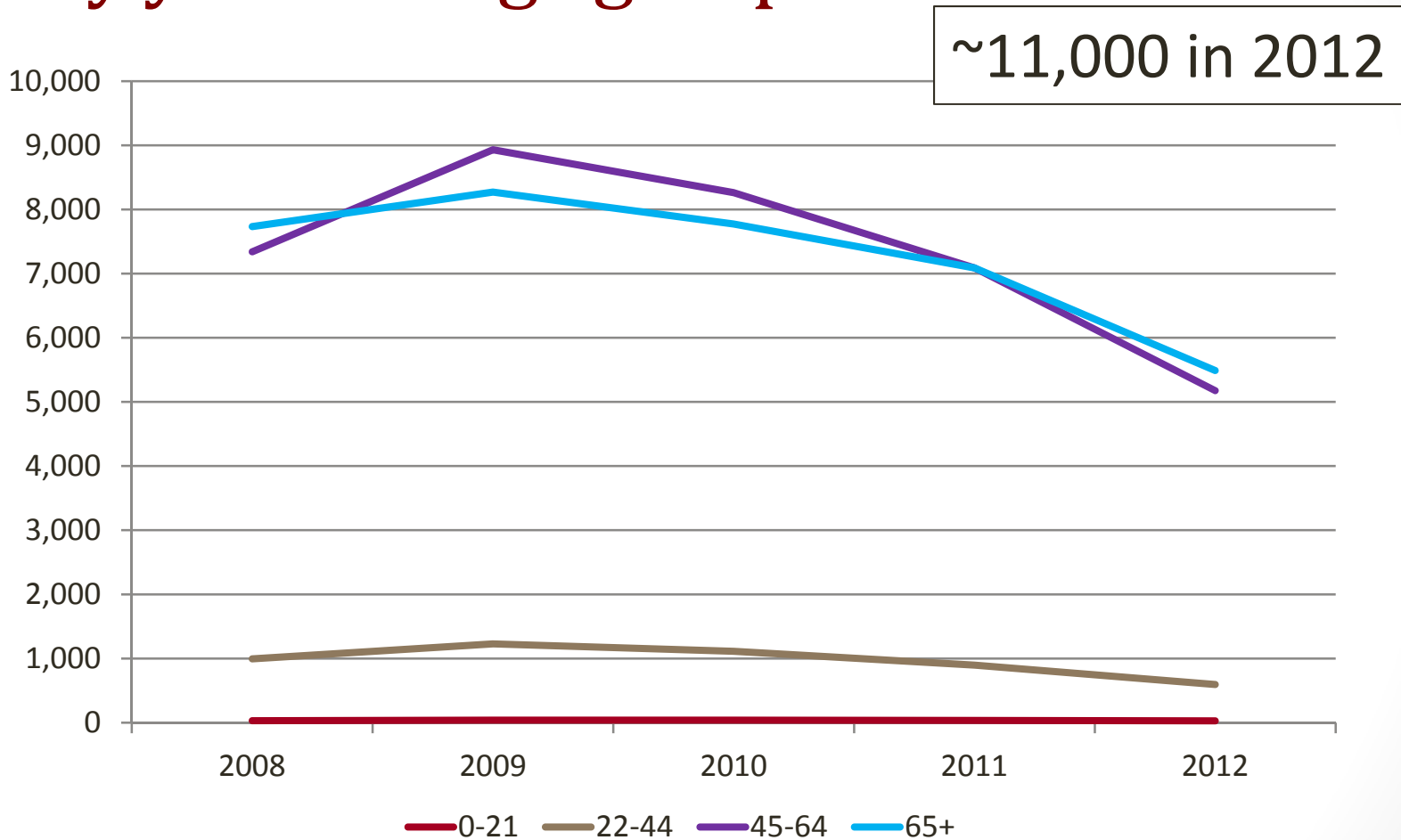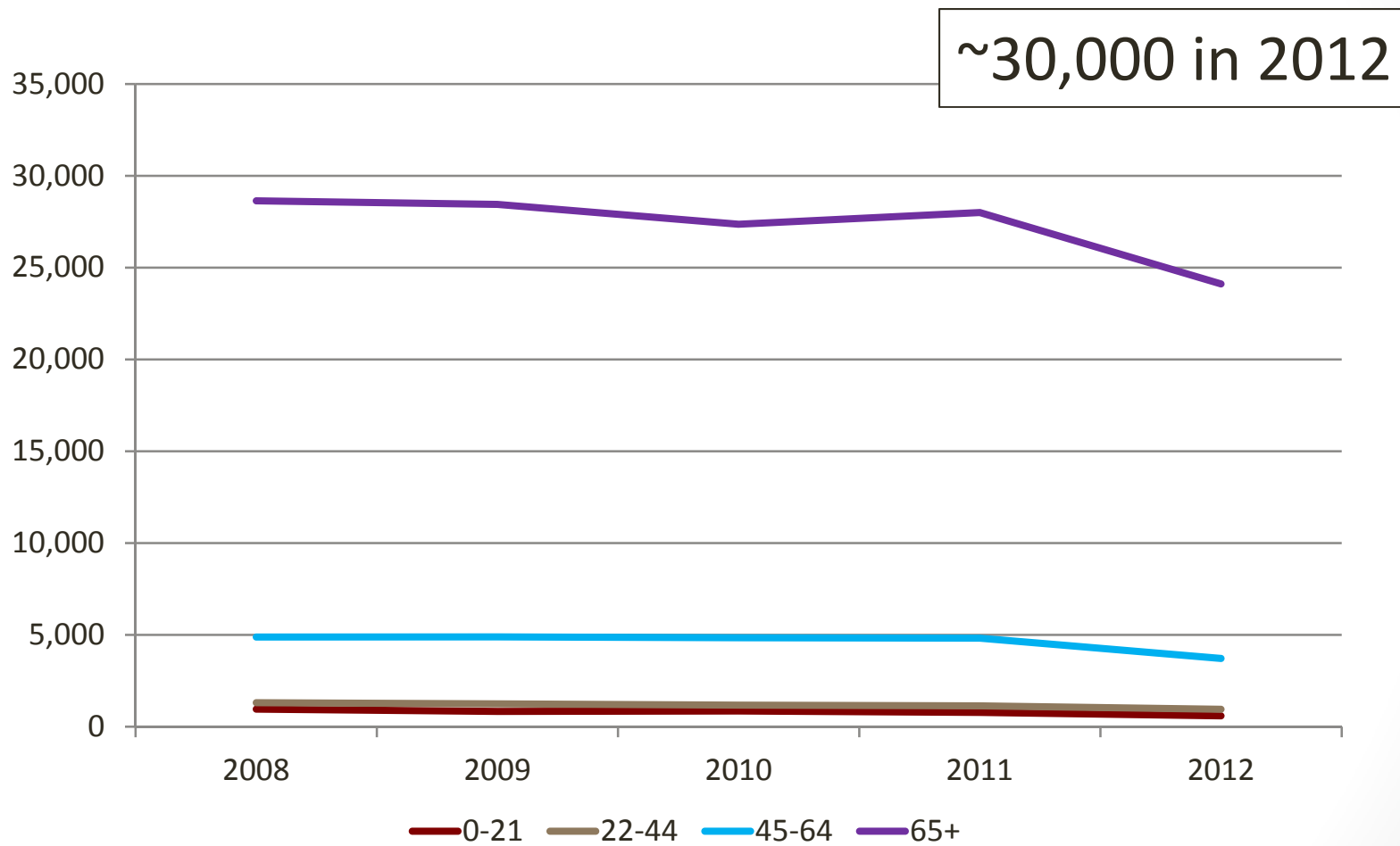
Vertebral fracture w/o injury to spinal cord*

~22,000 in 2012

*Prevalence

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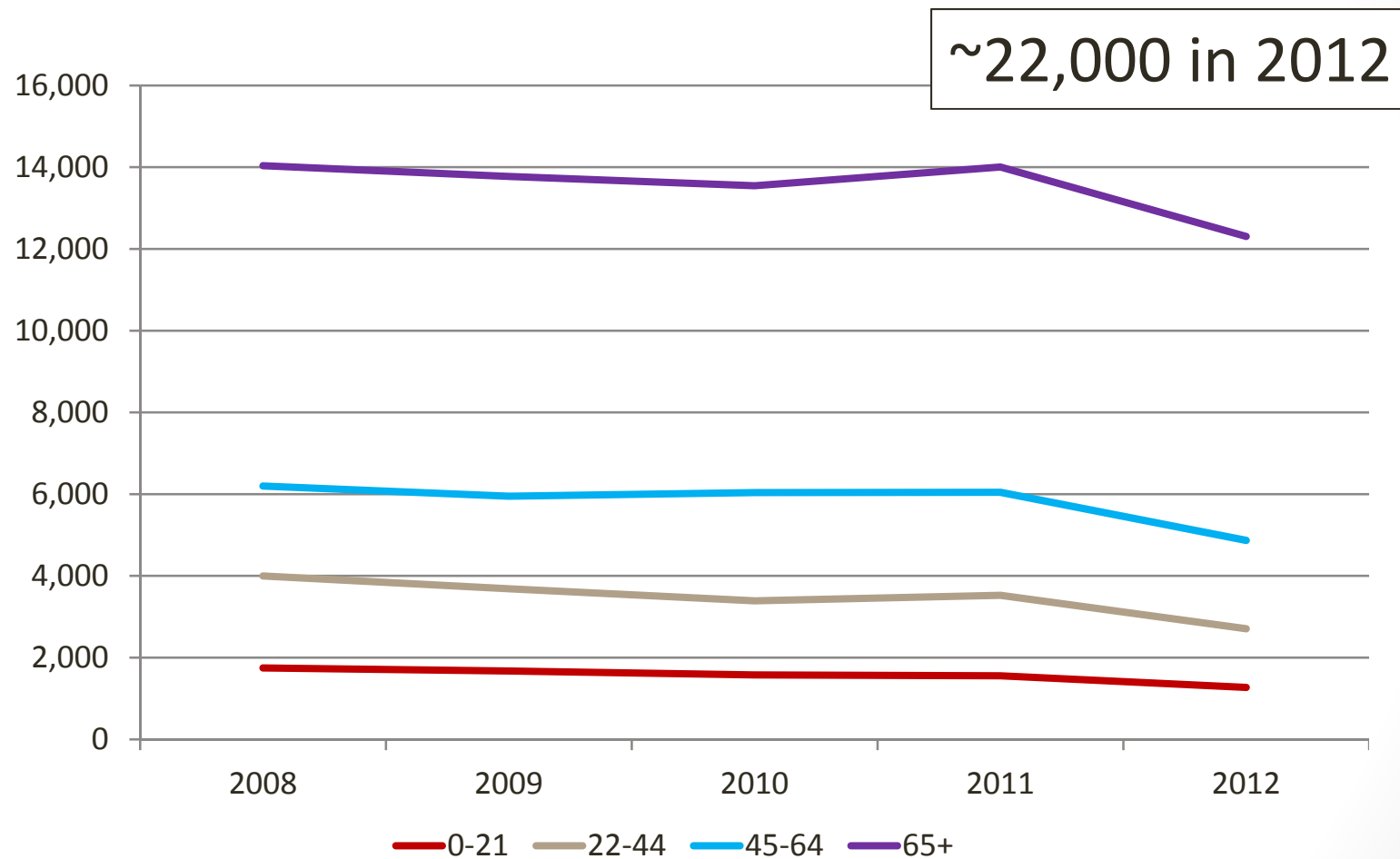
Vertebral fracture with injury to spinal cord*

~2,900 in 2012

*Prevalence

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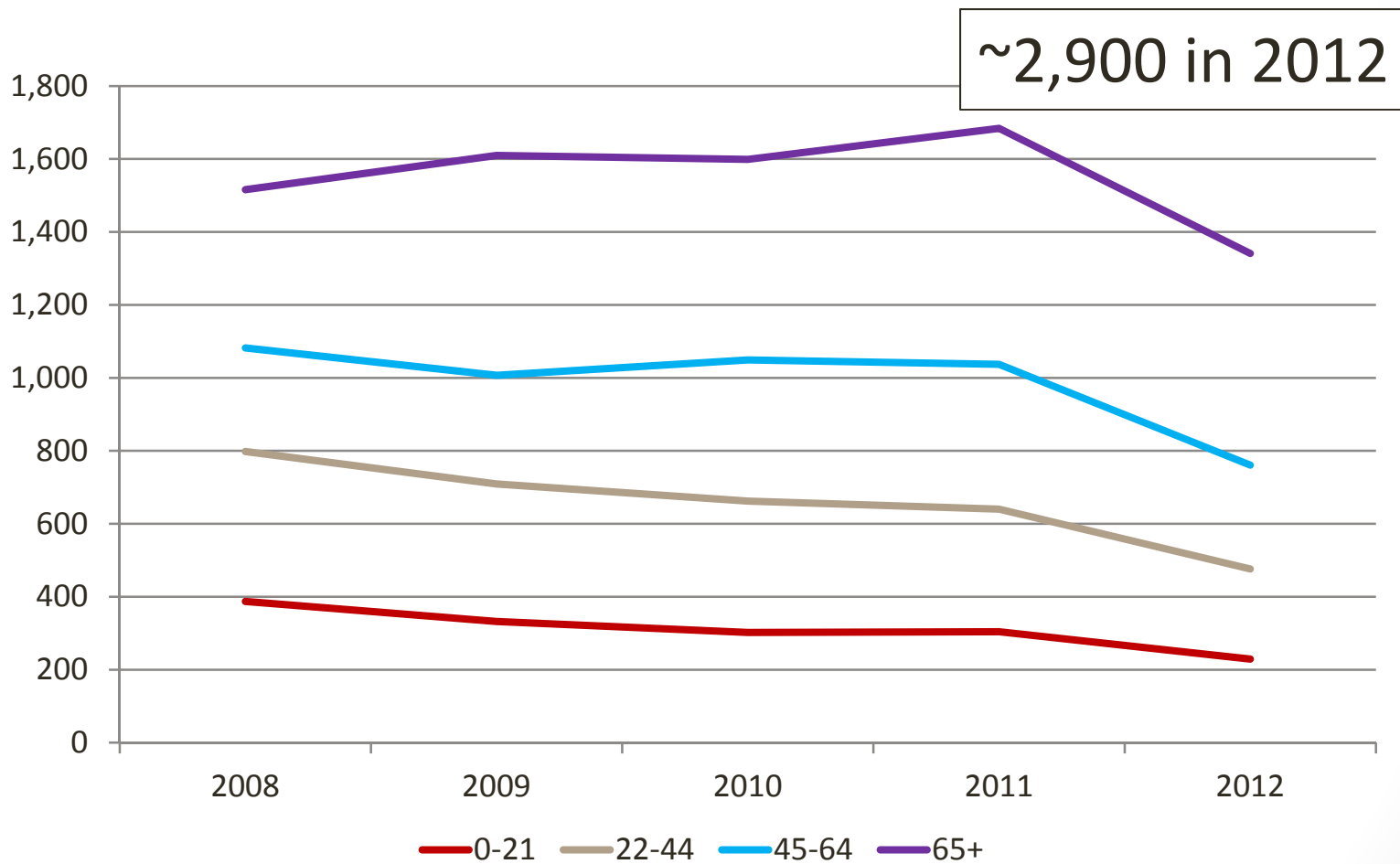
Standardized query of patient-level data

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

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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
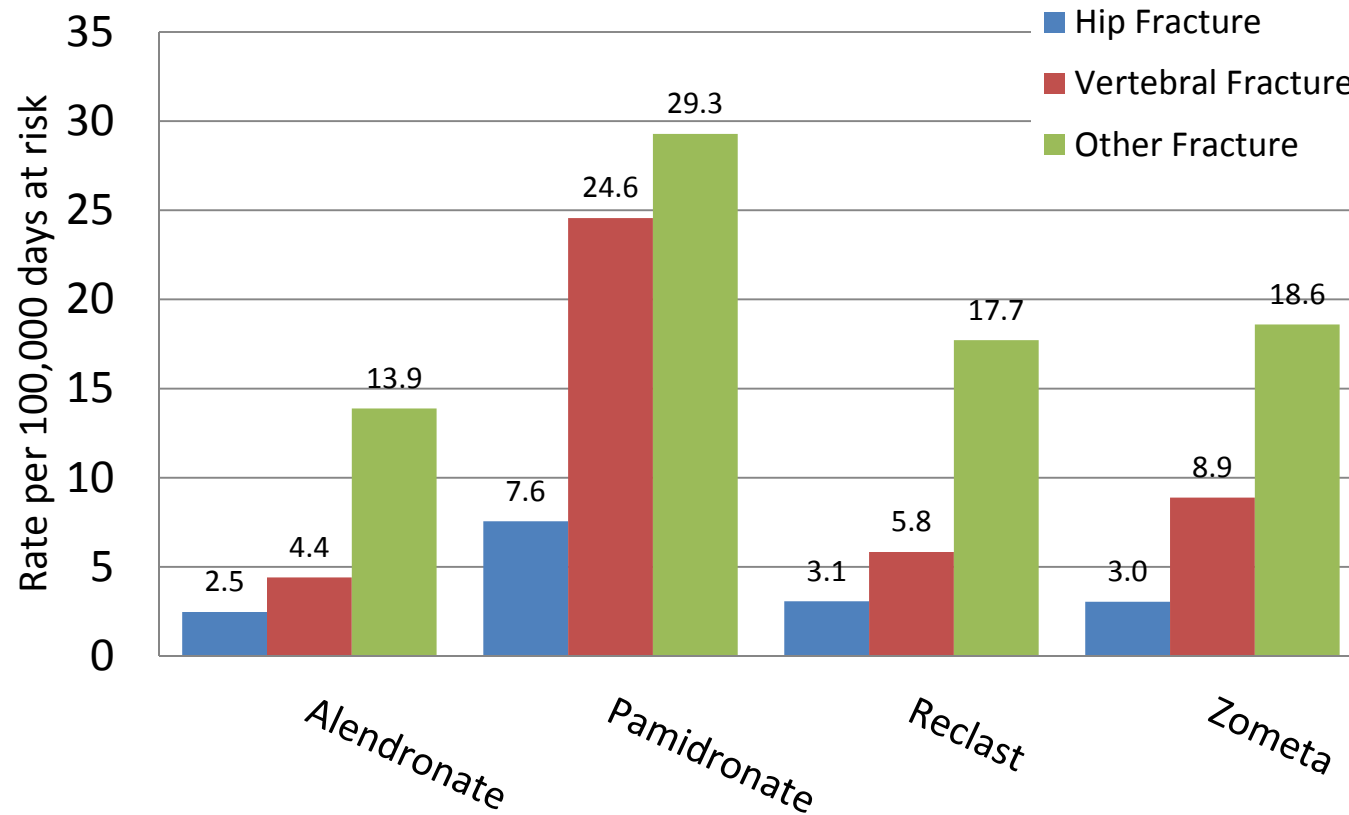
Incident users

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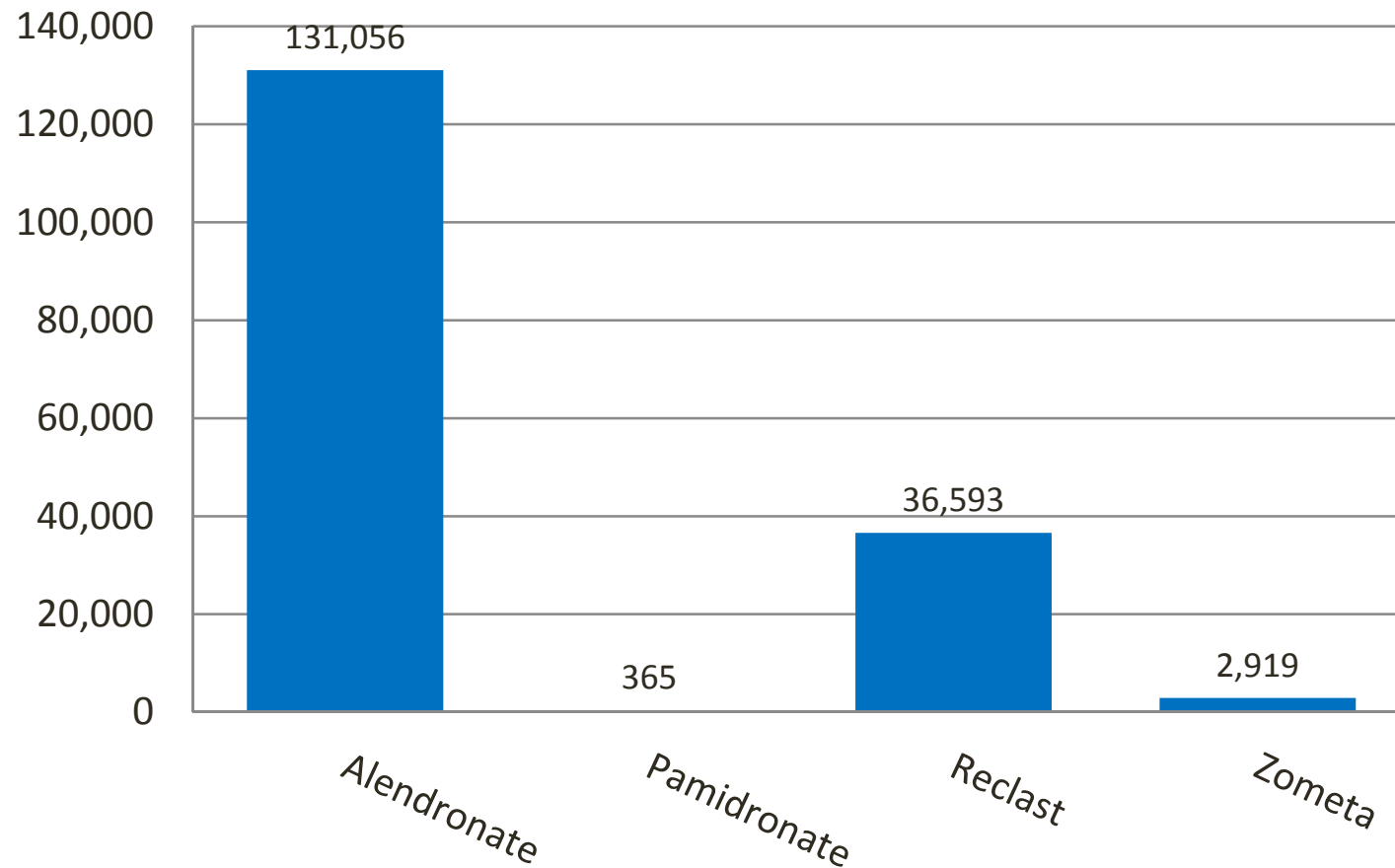
Fractures among incident users
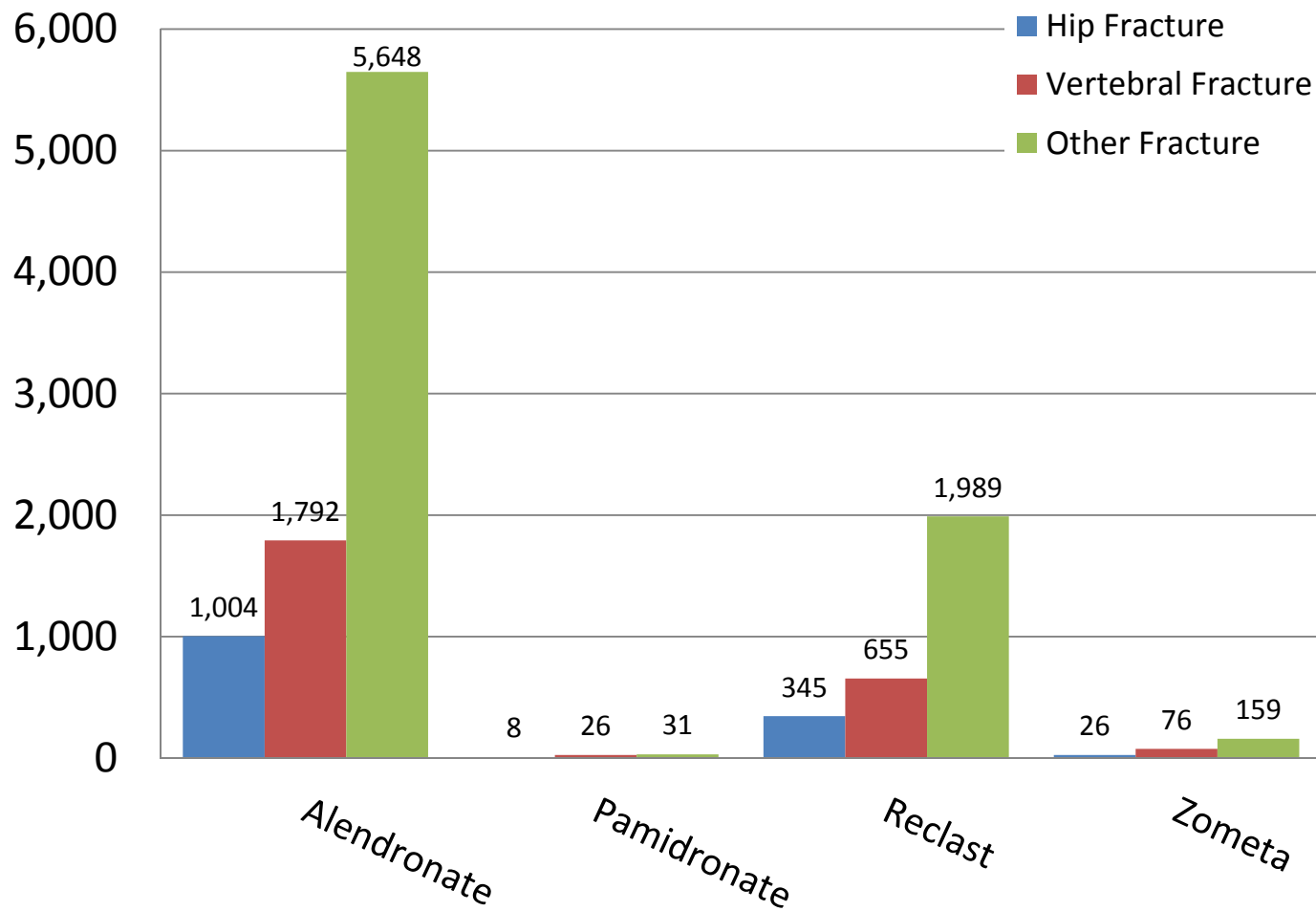
Fracture rate among incident users (per 100,000 days at risk)*

*Unadjusted

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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

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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

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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
- Pragmatic clinical trial follow up
- Reuse of research data

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Thank You

For more information

- nihcollaboratory.org/Pages/distributed-research-network.aspx

- PopMedNet.org

- info@nihquery.org

- Jeff_brown@harvardpilgrim.org

Prior Grand Rounds

June 28, 2013

https://www.nihcollaboratory.org/Pages/Grand-Rounds-06-28-13.aspx

March 15, 2013

https://www.nihcollaboratory.org/Pages/Grand-Rounds-03-15-13.aspx

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