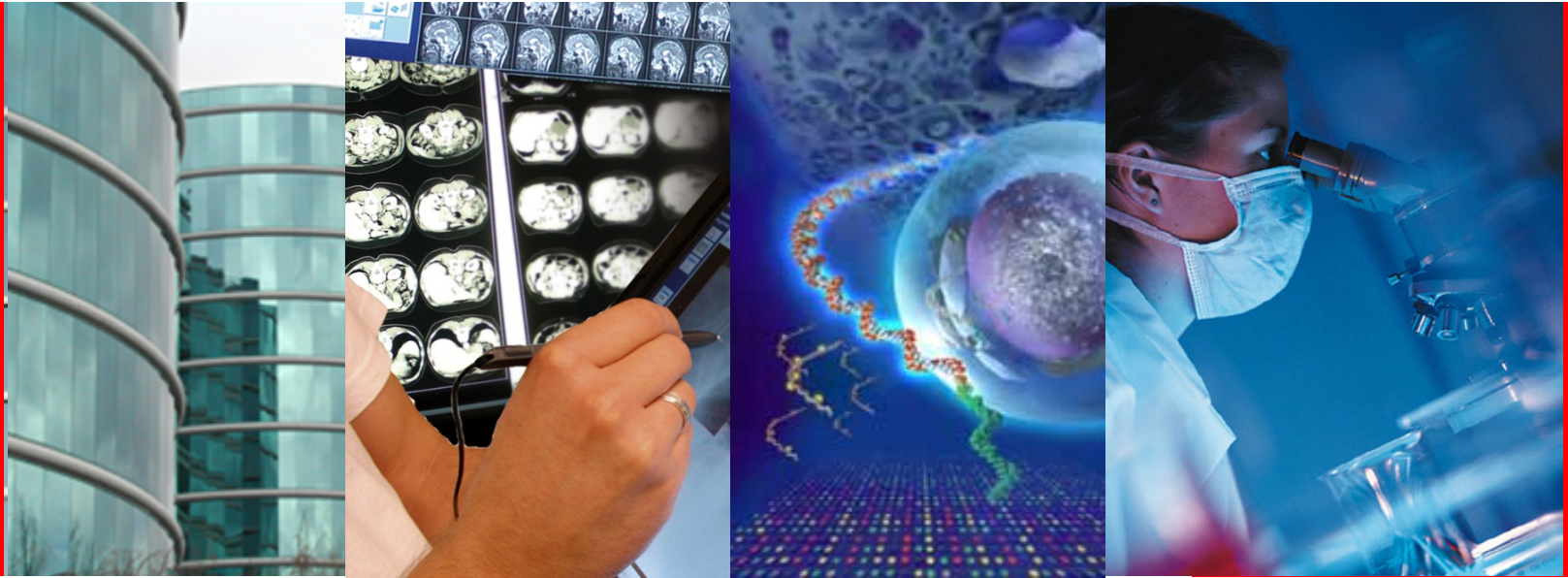




ORACLE®

HEALTH SCIENCES

PHUSE Conference – Health Sciences Network

October 2013

Safe Harbor Statement

The following is intended to outline our general product direction. It is intended for information purposes only, and may not be incorporated into any contract. It is not a commitment to deliver any material, code, or functionality, and should not be relied upon in making purchasing decisions.

The development, release, and timing of any features or functionality described for Oracle's products remains at the sole discretion of Oracle.

Abstract

I have very specific requirements for a clinical trial.

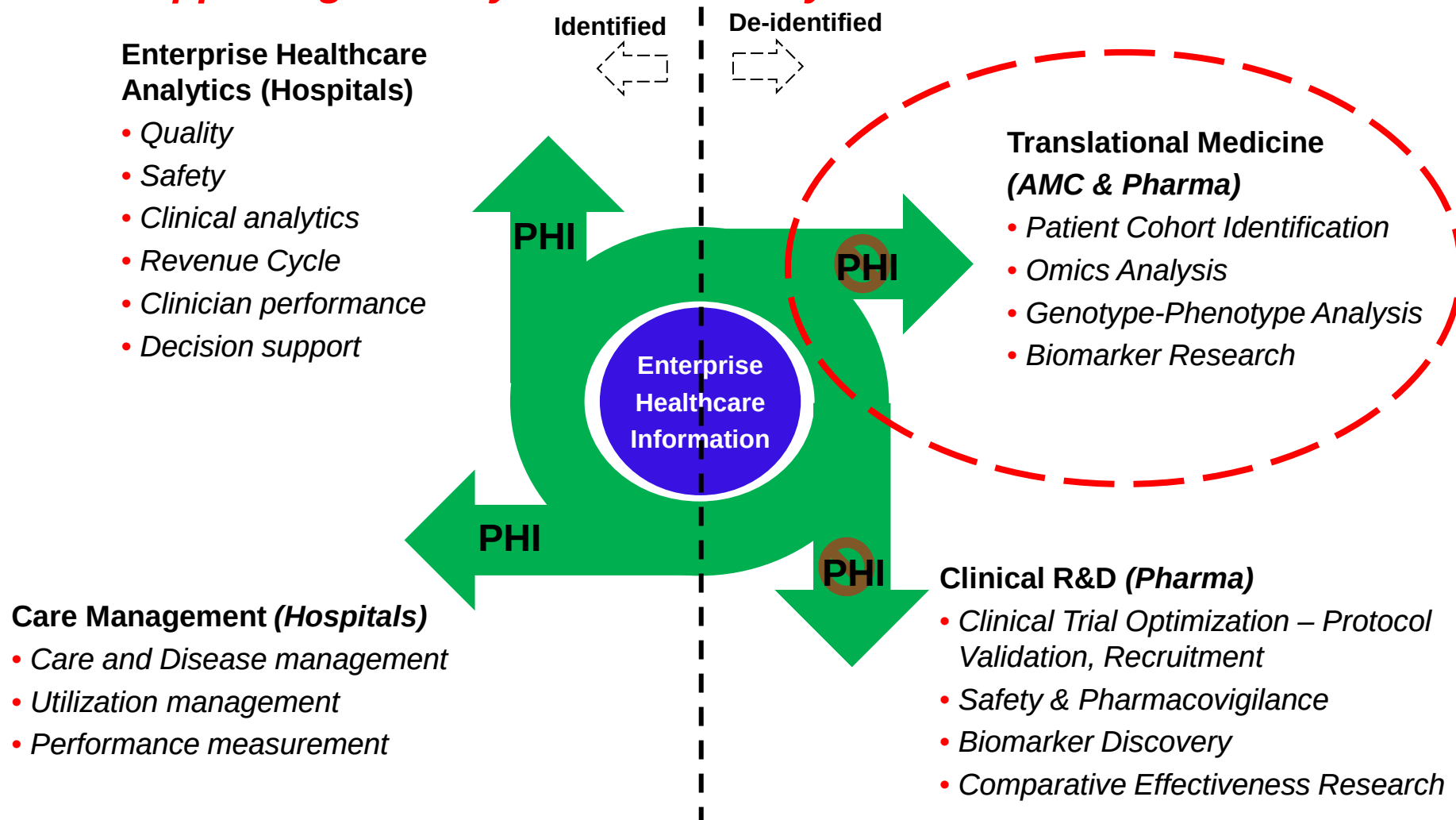
- am I going to be able to find enough subjects?
- how can I find and recruit eligible patients?

With the wealth of information available in healthcare records, and from an increase in the use of gene sequencing technology, it is now feasible to search large data sets to find patients who can satisfy much more specific eligibility requirements for a clinical trial.

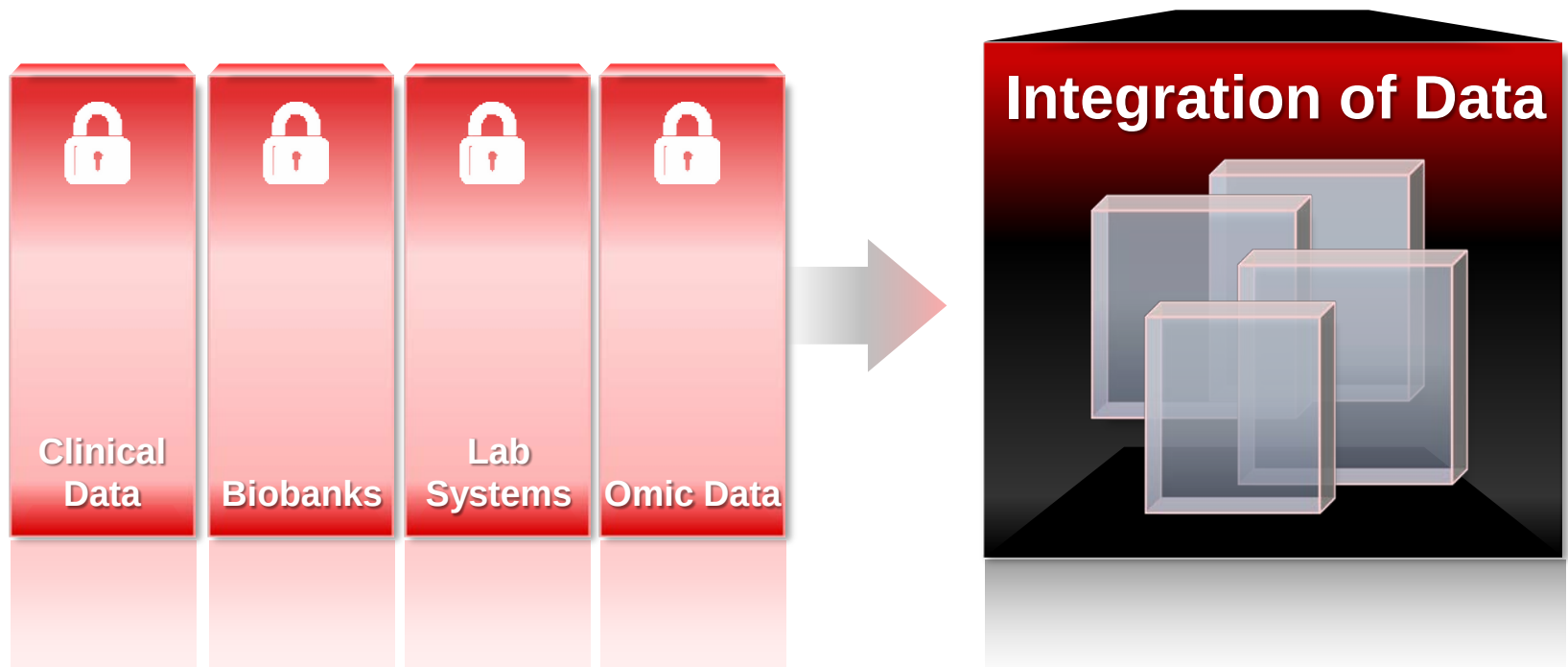
We will demonstrate how, using a warehouse based approach, we can validate a trial protocol, select a study cohort and help identify and recruit the cohort into the study.

Oracle's Healthcare Platform

Supporting Primary and Secondary Uses of Data

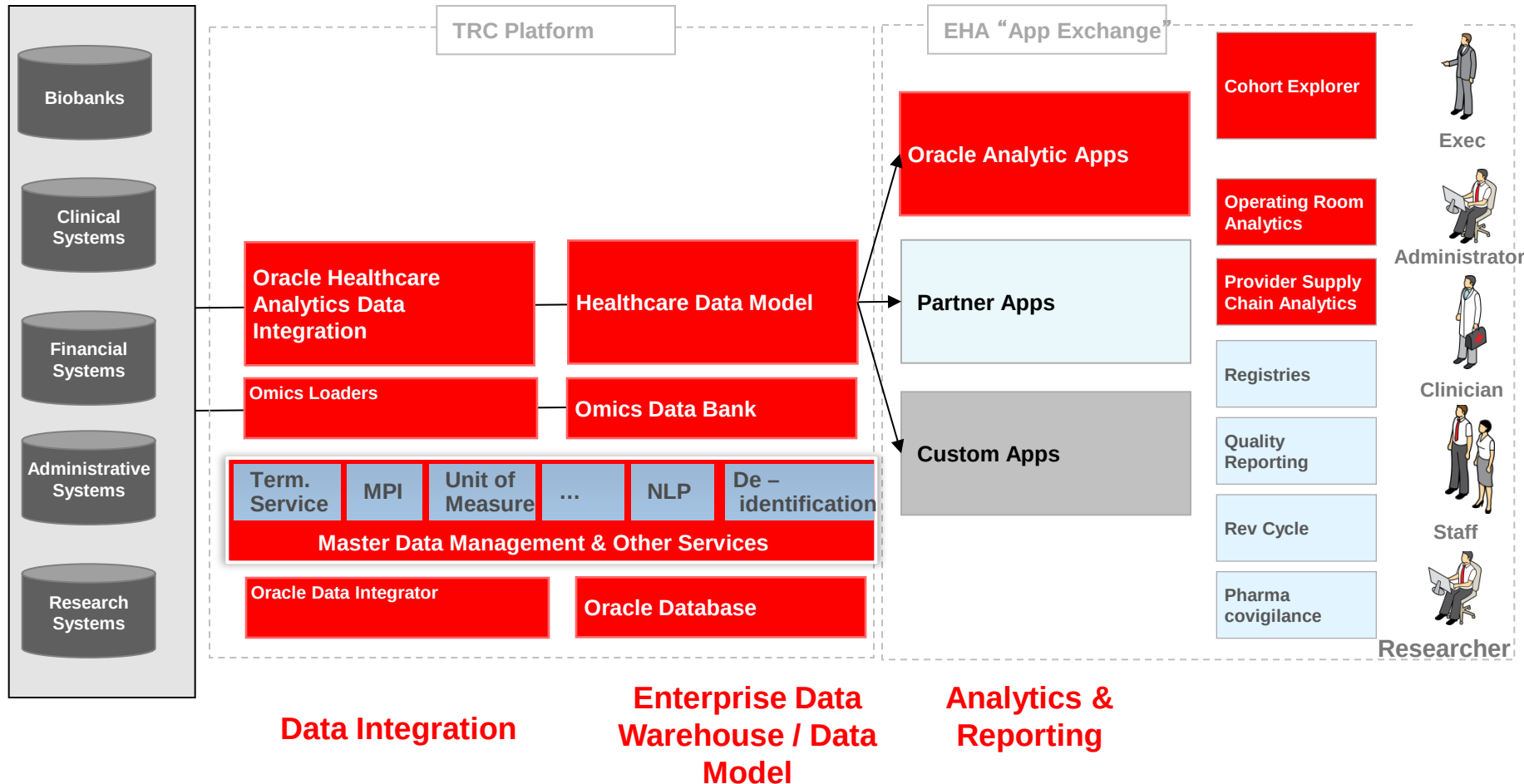


Turn Silos of Data Into Information That Speed Discovery Time



Oracle Enterprise Healthcare Analytics

Translational Research Center



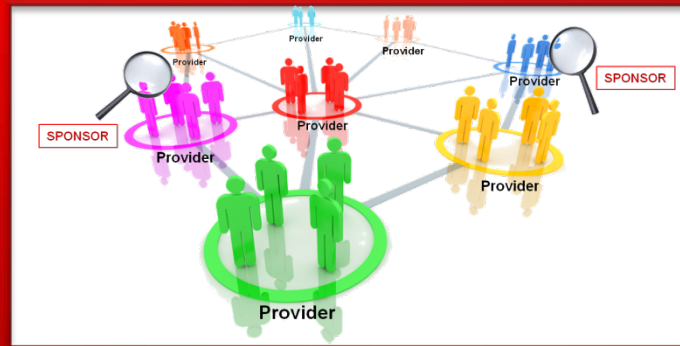
Oracle Health Sciences Network

Secure HIPAA certified Cloud-based
Collaboration for Clinical R&D

Healthcare Provider
Participants

Alerts

De-identified Data



Protocols

Life Sciences
Participants

Near Real-Time Clinical Data

Protocol Feasibility / Validation & Patient Recruitment

More use cases to come ...

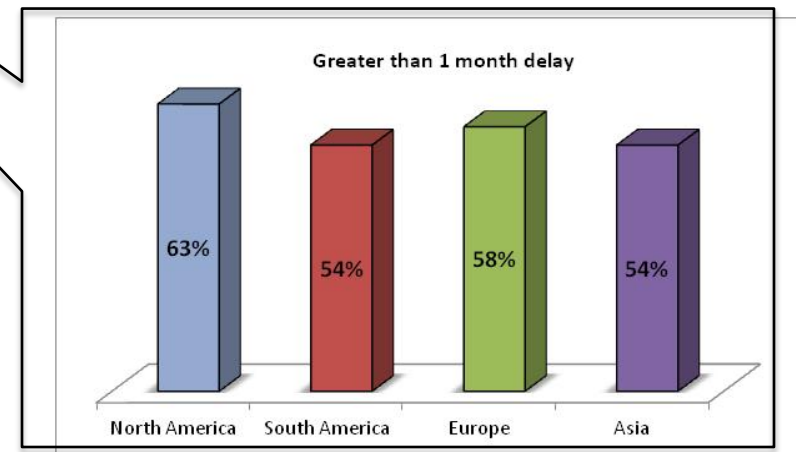
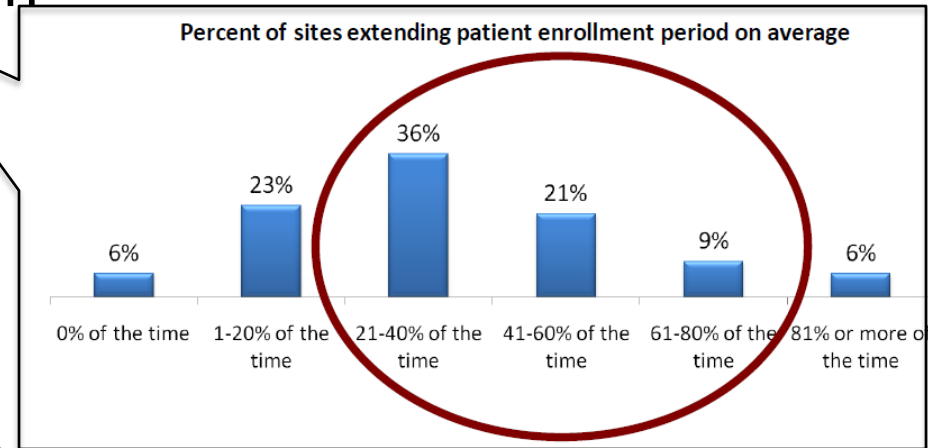
ORACLE

Business Problem

- Patient enrollment extension

- Clinical trial delays
 - Slow & unpredictable

- 1 day delay in Development
 - \$37,000 operation cost
 - \$1.1M of prescription revenue



Opportunities of EHR in Trial Design

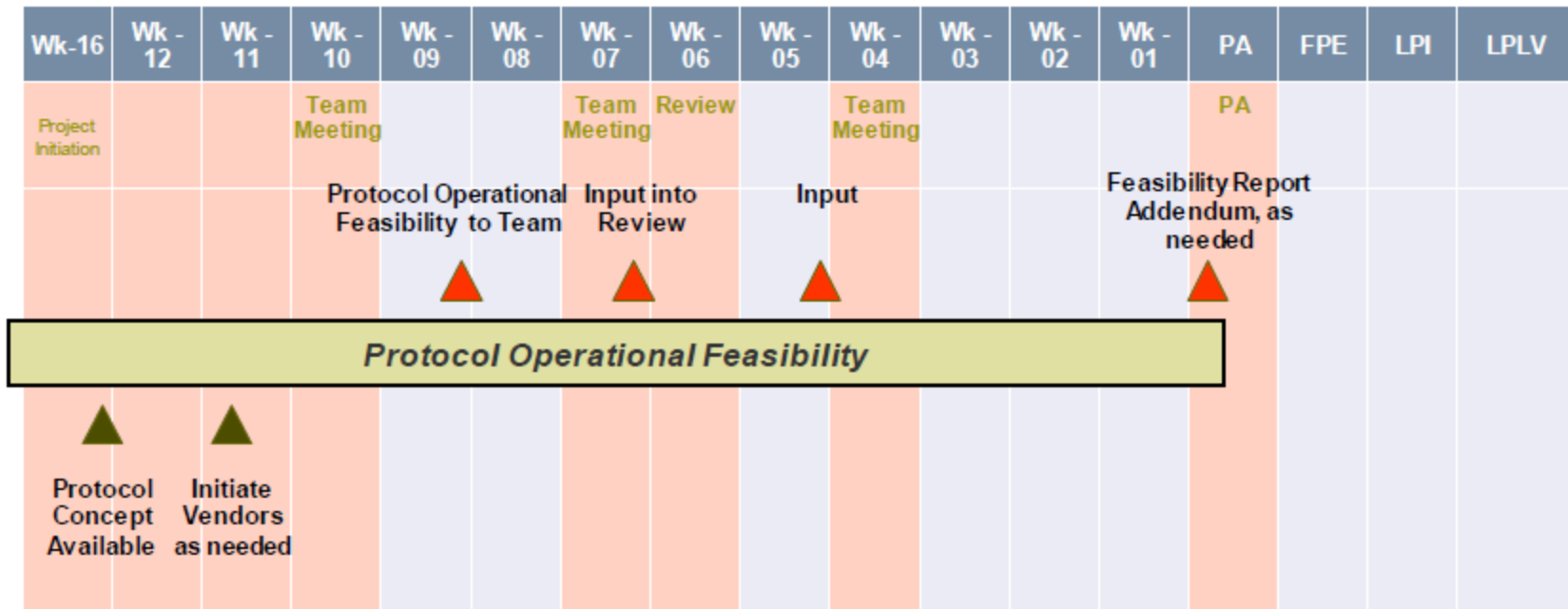
- Applicable in: Pre-clinical, Phase I, II, III, & Post launch
- Quality information for cross functional influencers
 - Clinical trial team
 - Product project managers
 - Product and brand teams
- Ability to influence decisions with quality information
 - Study feasibility
 - Recruitment modeling
 - Identify target sites
- Protocol complexity and impact on cycle time

Impacting Trial Performance

- Site failure
- Site initiation period
- Screening rate
- Screen failure
- Site enrollment capacity

When is EMR analysis needed?

Protocol Operational Feasibility



HSN recruitment model

Passive Trial

Patients must find investigator

- Advertisements
- Chance clinic visit



Active Trial

Candidate Alert

HSN alerts investigating team to potential subject



Investigating team locates subject across provider and alerts treating physician as to trial opportunity



Future: investigating team directly alerts patients across the system about a clinical trial

Recruitment

Physician and patient discuss opportunity



Investigators screen and enroll patient



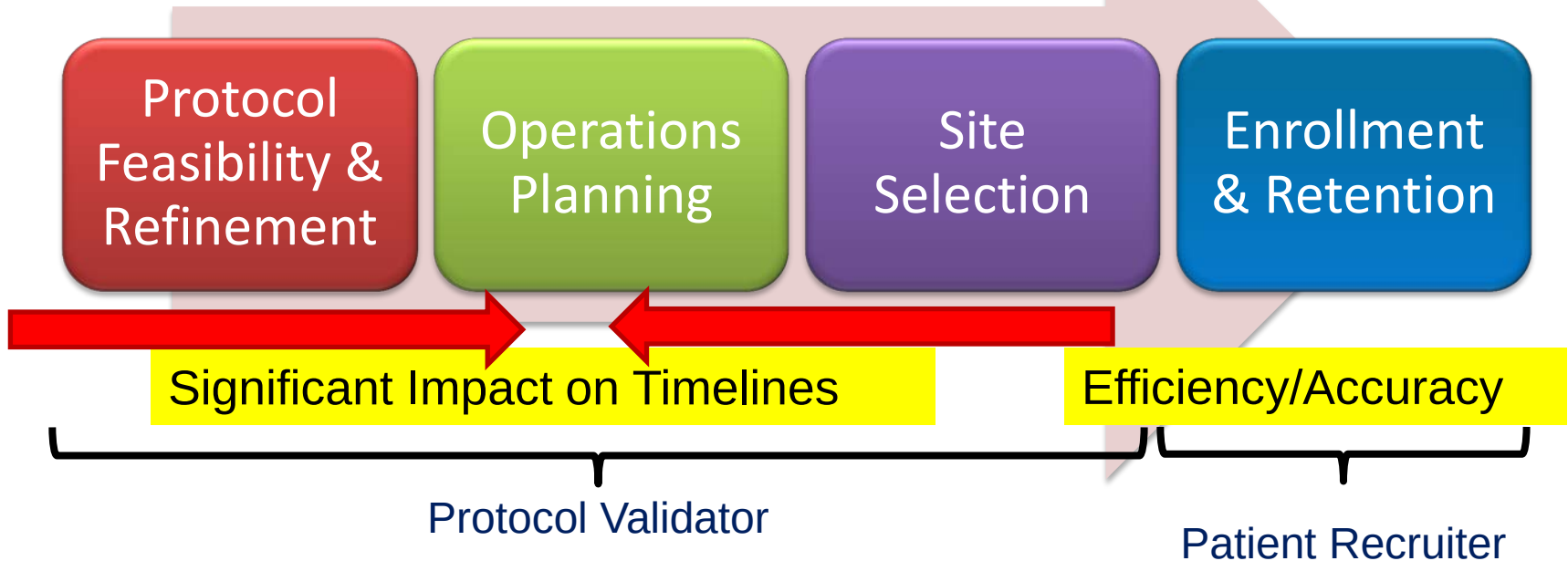
Oracle Health Sciences Network Offerings

- **Protocol Validator Cloud Service**

- **Patient Recruiter Cloud Service**

Value proposition for pharma or sponsor

Lowering costs and speeding time to market



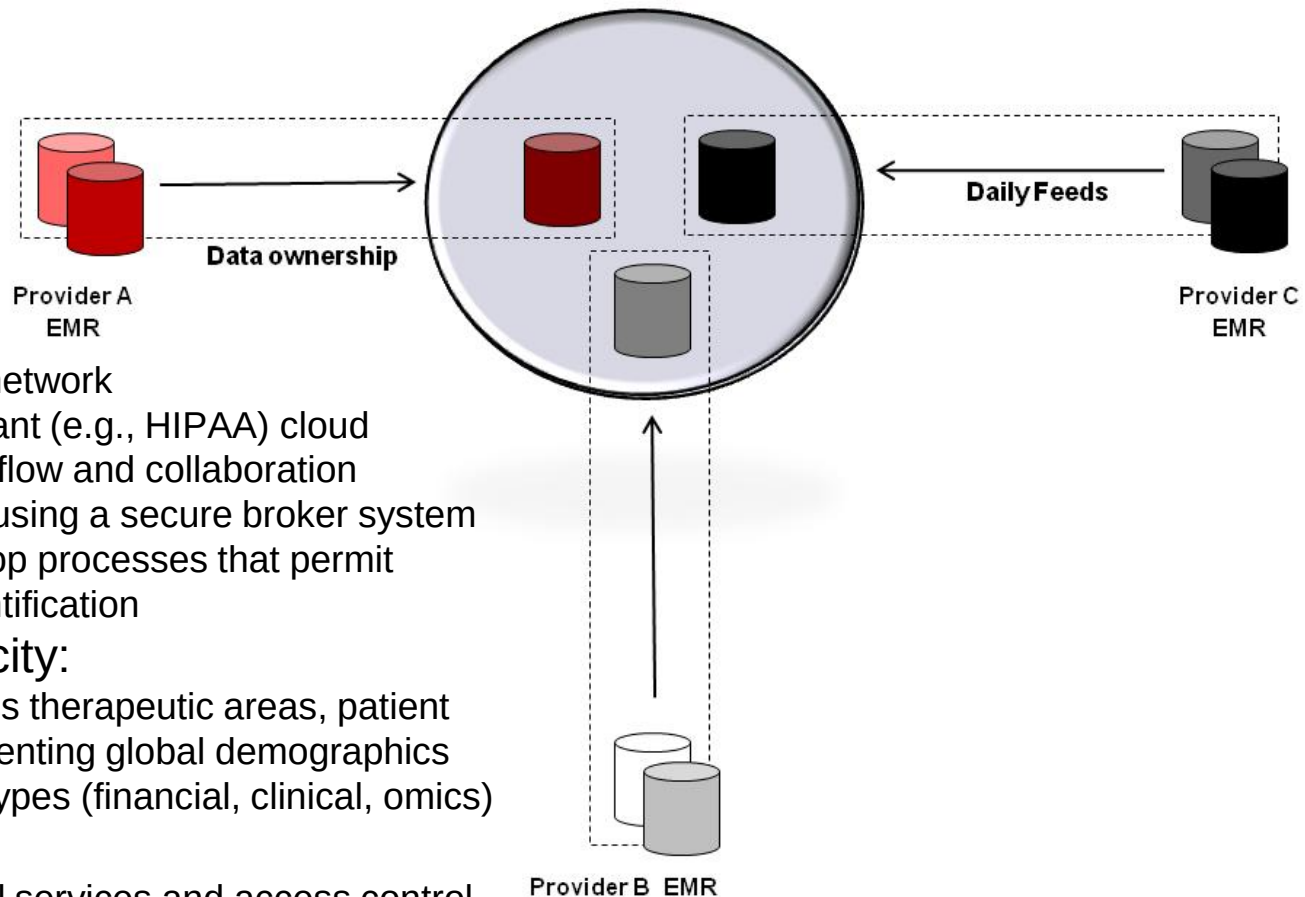
- Near real-time data shared by participants
- Protocol feasibility and validation results in seconds
- Sponsors share protocols with provider and tie patients to sites/physicians instantaneously

HSN Value Proposition

- Direct access to high quality near real-time clinical information
- Select providers to perform instant study feasibility analytics
- Share protocols with select providers to further validate the protocols
- Having sites involved early in the protocol process
- Qualify patients jointly with providers based on quality longitudinal information
- Providers have ability to re-identify patients for recruitment
- Initiate a system wide recruitment process
- Improve percentage of patients recruited per site metric
- Speed IRB approval times

HSN: Differentiators & Design Principles

Health Sciences Network

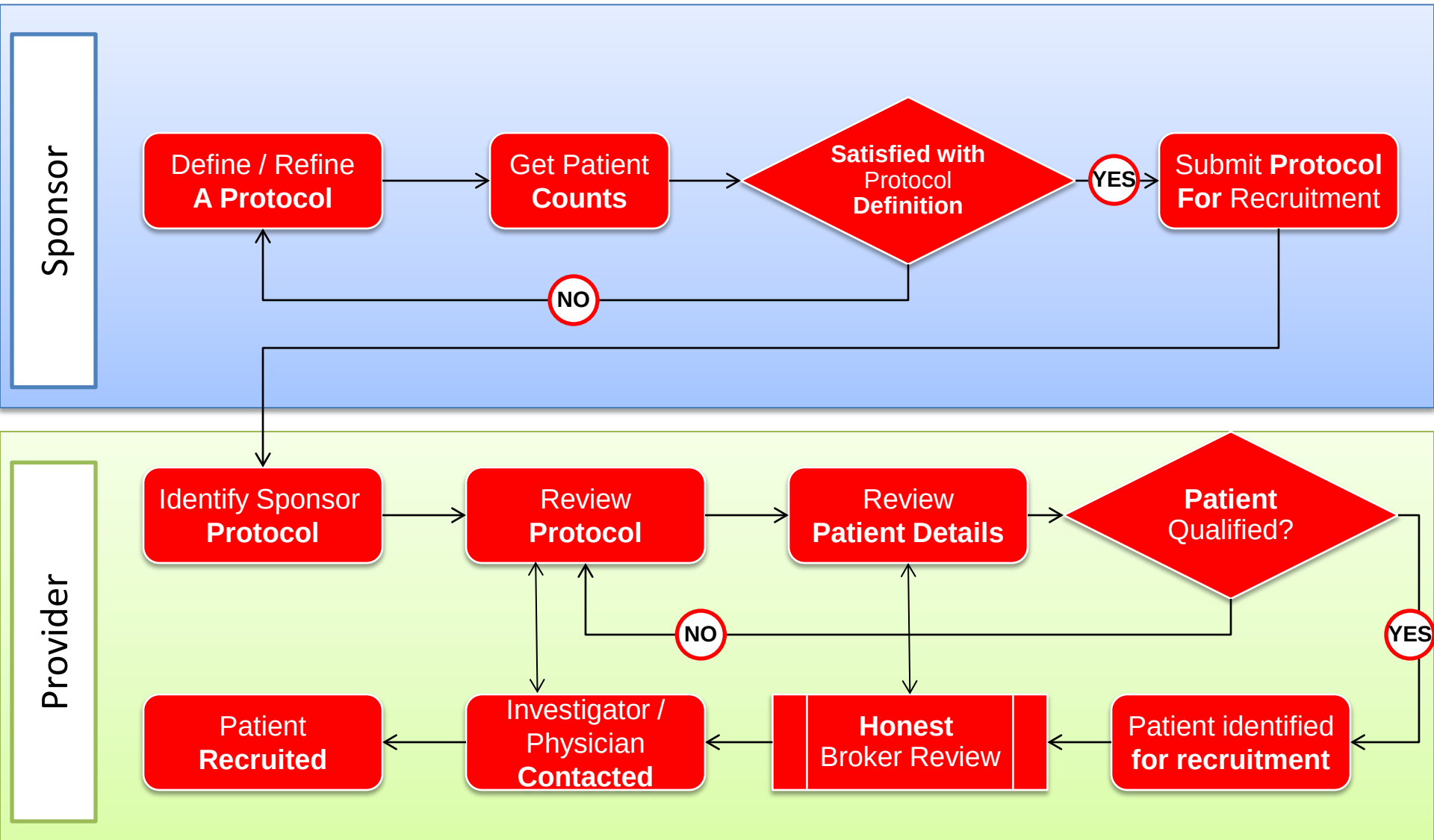


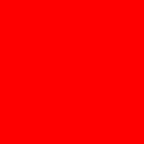
- **Confidence:**
 - Secure, real-time network
 - Regulatory-compliant (e.g., HIPAA) cloud
 - Bi-directional data flow and collaboration
 - Data de-identified using a secure broker system enabling closed loop processes that permit appropriate re-identification
- **Scale and Specificity:**
 - Global reach across therapeutic areas, patient populations representing global demographics and multiple data types (financial, clinical, omics)
- **Control:**
 - Participants control services and access control policies
 - Primarily a federated model, with aggregation of data only as necessary

Data mining in EMR Vs. HSN

- EMR data
 - Identifiable and patient visit focused
 - Tracks what happened each time the patient visited the provider
 - Each visit adds distinct additions around a single patient
 - Operational model not ideal for mining
 - Difficult to characterize across a cohort of patients
- HSN data
 - Detailed de-identified longitudinal data sets across Demographics, Diagnosis history, Procedure history, Medication history, Lab Value history, and Consent /Consent Sample info
 - Temporal query capabilities
 - Architected for analytics

PVPR Value Based Process Flow





Screenshot demo

▼ Login Information

* User Name

* Password

Login

My Queries

Query Patients

Search Queries ?

Query Name

Content Creation Date 

Shared for Recruitment

[Search](#) [Reset](#)

case insensitive, returns first 500 matches

[Load Query](#)

[Share For Recruitment](#)

[Recall Recruitment](#)

	Query Name	Content Creation Date	Shared for Recruitment	Shared Date	Status	Status Update Date
▶	Follow up Consent GBM	02/12/2013 12:42 PM	No		NA	
▶	NCT01346579-65	02/12/2013 11:25 AM	Yes	02/12/2013 11:30 AM	Recruitment Ready	
▶	NCT01346579	02/12/2013 11:02 AM	No		NA	
▶	NCT01658332	02/12/2013 10:58 AM	No		NA	
▶	BRCA F ->70_ER+	01/04/2013 10:38 AM	Yes	01/04/2013 10:39 AM	In Progress	01/04/2013 10:47 AM
▶	Stage I breast Cancer older wom...	01/04/2013 09:27 AM	No		NA	
▶	Stage I breast cancer older wo...	01/04/2013 09:25 AM	No		NA	
▶	biomarkers in tissue samples for...	01/04/2013 09:23 AM	No		NA	

[My Queries](#)

Query Patients

Select Cohort Criteria

Patient Information

Demographics

Consent

> Clinical Data

Initial Patient Count 

7,683

▼ Inclusions 

No data to display.

▼ Exclusions 

No data to display.

 Clear

 Save Query

 Run Query

Patient Count 

[My Queries](#)

Query Patients

Select Cohort Criteria

> **Patient Information**

Clinical Data

Diagnosis

Procedure

Medication

Patient History

Diagnostic Test

Specimen

Relative Time Events

Initial Patient Count 

7,683

▼ **Inclusions **

No data to display.

▼ **Exclusions **

No data to display.

 Clear

 Save Query

 Run Query

Patient Count 

My Queries

Query Patients

Select Cohort Criteria ?

> Patient Information

Clinical Data

Diagnosis

Procedure

Medication

Patient History

Diagnostic Test

Specimen

Relative Time Events

Initial Patient Count ?

Diagnosis

* Diagnosis

Diagnosis Status

Onset Date between



and



Reported Date between



and



End Date between



and



Age At First Onset between

and

Anatomical Site



Insert as:

☒ inclusion

☐ exclusion

Reset

Cancel

Submit

Demographics

Patient ID

Gender **FEMALE**

Marital Status

Age (years) between **70** and

Date of Birth between and

Deceased Date between and

Select Diagnosis



Diagnosis Name **Contains**

Diagnosis Code **Starts with**

case insensitive, returns first 500 matches

	Code	Name
▷	254838004	Carcinoma of breast
▷	278053004	Infiltrating Ductal carcinoma of breast
▷	278054005	Infiltrating Lobular carcinoma of breast

Code	Name
No data to display.	

Select Specimen Type



Specimen Type Name **Contains** tumor

Specimen Type Code Starts with

Search

Reset

case insensitive, returns first 500 matches

Code	Name
▶ PT	Primary Tumor

Code	Name
PT	Primary Tumor

Diagnostic Test

* Diagnostic Test **ER + Status(ER + Status)**

Test Date between and

Result (Numeric) between and

Units

Result String **Positive(Positive)**

Insert as:

- ☒ inclusion
☐ exclusion

Reset

Cancel

Submit

Age is greater than or equal to 70

[My Queries](#) **Query Patients**

Select Cohort Criteria ?

Patient Information

Demographics

Consent

> Clinical Data

Initial Patient Count ?

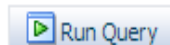
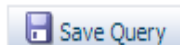
7,683

▼ Inclusions ?

▼	☒ Diagnosis			
	Diagnosis is Carcinoma of breast(254838004), Infiltrating Ductal carcinoma of breast(278053004), or Inf...			
▼	☒ Diagnostic Test			
	Diagnostic Test is ER + Status(ER + Status)			
	Result String is Positive(Positive)			
▼	☒ Specimen			
	Specimen Type is Primary Tumor(PT)			
▼	☒ Consent			
	Consent Type is Health Questionnaire(HQ) or Sample Acquisition Consent(SAC)			
▼	☒ Demographics			
	Gender is FEMALE			
	Age is greater than or equal to 70			

▼ Exclusions ?

No data to display.



Patient Count ?

12

Last query loaded or saved: NCT01346570

My Queries

Query Patients

Search Queries ?

Query Name

Content Creation Date

Shared for Recruitment

Search

Reset

case insensitive, returns first 500 matches

Load Query

Share For Recruitment

Recall Recruitment

	Query Name	Content Creation Date	Shared for Recruitment	Shared Date	Status	Status Update Date
▶	NCT01346579-65	02/12/2013 11:25 AM	No		NA	
▶	NCT01346579	02/12/2013 11:02 AM	No		NA	
▶	NCT01658332	02/12/2013 10:58 AM	No		NA	



▼ Search Queries ?

Query Name Starts with Content Creation Date On or after Shared for Recruitment Equals

case insensitive, returns first 500 matches



	Query Name	Content Creation Date	Shared for Recruitment	Shared Date	Status	Status Update Date
▶	NCT01346579-65	02/12/2013 11:25 AM	Yes	02/12/2013 11:30 AM	Recruitment Ready	
▶	NCT01346579	02/12/2013 11:02 AM	No		NA	
▶	NCT01658332	02/12/2013 10:58 AM	No		NA	

Recruitment Requests

Query Patients

Patient Viewer

Search Recruitment Request ?

Query Name

Submit Date

Requestor

Status

Status Updated By

[Search](#) [Reset](#)

case insensitive, returns first 500 matches

[Load Query](#)

[Update Status](#)

Query Name	Submit Date	Requestor	Status	Status Updated Date	Status Updated By
▶ NCT01346579-65	02/12/2013 11:30 AM	validator	Recruitment Ready		

Search Recruitment Request ?

Query Name	Starts with	
Submit Date	On or after	01/13/2013 12:54 PM 
Requestor	Starts with	
Status	Equals	
Status Updated By	Starts with	

case insensitive, returns first 500 matches

Load Query

Update Status

Update Status

Query Name: NCT01346579-65

Status ☒ Recruitment Ready
☐ In Progress
☐ Done

OK

Cancel

Query Name

Submit Date

NCT01346579-65

01/13/2013 12:54 PM

Recruitment Requests

Query Patients

Patient Viewer



Initial Patient Count 

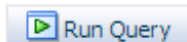
7,683

Inclusions

☒	Diagnosis	Diagnosis is Carcinoma of breast(254838004), Infiltrating Ductal carcinoma of breast(278053004), or Infiltrating Lobular carcinoma of breast(27805...			
☒	Diagnostic Test	Diagnostic Test is ER + Status(ER + Status)			
		Result String is Positive(Positive)			
☒	Specimen	Specimen Type is Primary Tumor(PT)			
☒	Consent	Consent Type is Health Questionnaire(HQ) or Sample Acquisition Consent(SAC)			
☒	Demographics	Gender is FEMALE			
		Age is greater than or equal to 65			

Exclusions

No data to display.



Patient Count 

Last query loaded or saved: **NCT01346579-65**

ORACLE Health Sciences Network

Recruitment Requests Query Patients

Patient List Patient Timelines Single Patient

Show

Patients

IDs from:

☒ active query 25

Data

Submit

ORACLE Health Sciences Network

Recruitment Requests Query Patients

Patient List Patient Timelines Single Patient

Show

Patients

Data

☒ Shared ID

☐ Demographics

☐ Diagnosis

☐ Procedure

☐ Medication

☐ Diagnostic Test

☐ Consent

☐ History or Risk Factor

☐ Specimen Collection

Submit

Recruitment Requests

Query Patients

Patient Viewer

Patient List

Patient Timelines

Single Patient

Show 

> Patients

Data

- ☐ Shared ID
- ☒ Demographics
- ☒ Diagnosis
- ☐ Procedure
- ☐ Medication
- ☐ Diagnostic Test
- ☐ Consent
- ☐ History or Risk Factor
- ☒ Specimen Collection

Patient ID	Age (years)	Gender	Event Type	Event Name	Event Co
250001	84	FEMALE	Diagnosis	Infiltrating Ductal c...	27805300
			Specimen	Primary Tumor	PT
			Specimen	Blood Derived Normal	BDN
250004	68	FEMALE	Diagnosis	Infiltrating Ductal c...	27805300
			Specimen	Primary Tumor	PT
			Specimen	Blood Derived Normal	BDN
250005	69	FEMALE	Diagnosis	Infiltrating Ductal c...	27805300
			Specimen	Primary Tumor	PT
			Specimen	Blood Derived Normal	BDN
250007	73	FEMALE	Diagnosis	Infiltrating Ductal c...	27805300
			Specimen	Primary Tumor	PT
			Specimen	Blood Derived Normal	BDN
250009	69	FEMALE	Diagnosis	Infiltrating Ductal c...	27805300
			Specimen	Primary Tumor	PT
			Specimen	Blood Derived Normal	BDN
250012	80	FEMALE	Diagnosis	Infiltrating Ductal c...	27805300
			Specimen	Primary Tumor	PT
			Specimen	Blood Derived Normal	BDN

Submit

 Export

 Print 

Patient Count

25

[Recruitment Requests](#) [Query Patients](#) **Patient Viewer**

Patient List [Patient Timelines](#) [Single Patient](#)

Show 

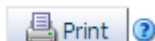
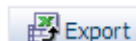
> Patients

Data

- ☒ Shared ID
- ☒ Demographics
- ☒ Diagnosis
- ☐ Procedure
- ☐ Medication
- ☐ Diagnostic Test
- ☐ Consent
- ☐ History or Risk Factor
- ☒ Specimen Collection

Patient ID	Shared ID	Age (years)	Gender	Event Type	Event Name
250001	TCGA-250001	84	FEMALE	Diagnosis	Infiltrating
				Specimen	Primary T
				Specimen	Blood Der
250004	TCGA-250004	68	FEMALE	Diagnosis	Infiltrating
				Specimen	Primary T
				Specimen	Blood Der
250005	TCGA-250005	69	FEMALE	Diagnosis	Infiltrating
				Specimen	Primary T
				Specimen	Blood Der
250007	TCGA-250007	73	FEMALE	Diagnosis	Infiltrating
				Specimen	Primary T
				Specimen	Blood Der
250009	TCGA-250009	69	FEMALE	Diagnosis	Infiltrating
				Specimen	Primary T
				Specimen	Blood Der
250012	TCGA-250012	80	FEMALE	Diagnosis	Infiltrating
				Specimen	Primary T
				Specimen	Blood Der

Submit



Patient Count
25

← → ↻ localhost:7001/pvpr/faces/shell?_afWindowMode=0&_adf.no-new-window-redirect=true&Adf-Window-Id=w0&_afLoo ☆ ☰

ORACLE Health Sciences Network Patient Recruiter Cloud Service Home accessibility recruiter Sign Out 

Recruitment Requests Query Patients **Patient Viewer**

Patient List Patient Timelines **Single Patient**

* Patient ID 

[Recruitment Requests](#) [Query Patients](#) **[Patient Viewer](#)**

[Patient List](#) [Patient Timelines](#) **[Single Patient](#)**

* Patient ID 

▼ **Demographics**

Patient ID	Shared ID	Gender	Marital Status	Age	Date of Birth	Deceased Date	Ethnicity	Race
250001	TCGA-250001	FEMALE		84	5/28/1928			

> **Consent Forms Signed**

> **Qualifies for Protocols**

> **Patient History**

> **Patient Diagnosis**

> **Procedures or Treatments Undergone**

> **Medications Taken**

> **Diagnostic Tests**

▼ **Specimen Samples Collected**

					
Specimen Type Name	Specimen Type Code	Date Collected	Anatomical Site Name	Anatomical Site Code	Amount
Primary Tumor	PT	5/29/2007	Region of Breast	279005008	120

Recruitment Requests Query Patients **Patient Viewer**

Patient List **Patient Timelines** Single Patient

Show

Patients

IDs from:

☒ active query

☐ library query

Query Name

☒ ad-hoc

Patient ID

Make initial pool

Initial Pool
3

☐ All

☐ 120616

☐ 20071

☐ 20074

Display
Max 20

120616
20071
20074

Remove

> Data

Submit

Time Scale ☒ Auto

☐ From

To

Update

Align Data by Patient Event

Patient ID	Event	2005			2006				2007	
		Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2
120616	Diagnosis									
120616	Procedure									
120616	Procedure									
120616	Procedure									
120616	Medication									
20071	Diagnosis									
20071	Procedure									
20071	Procedure									
20071	Procedure									
20071	Medication									
20074	Diagnosis									
20074	Procedure									
20074	Procedure									
20074	Procedure									

[Previous 1 Next]



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