

Oracle Study Start Up

臨床試験立ち上げの最適化：効率的な施設選定のための戦略とは？

Akira Soma

Solution Director

CDISC authorized Instructor for SDTM Theory & Application

Chair of Japan CDISC Coordinating Committee (J3C)

Oracle Life Sciences

December 5th, 2024

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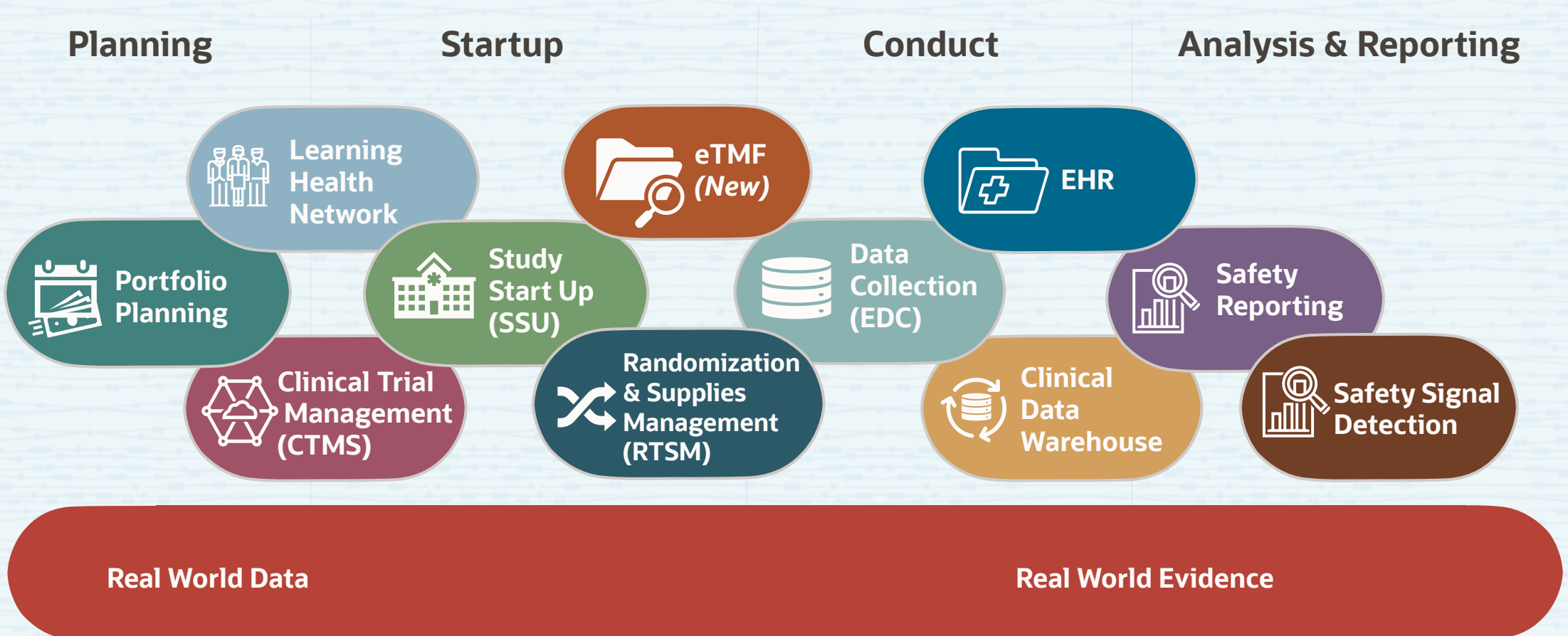


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Oracle Life Sciences Innovation Platform



Oracle Cloud Infrastructure

Data Lakehouse | Performance | Security | Scalability | Storage | Useability | AI & ML | Cost Savings

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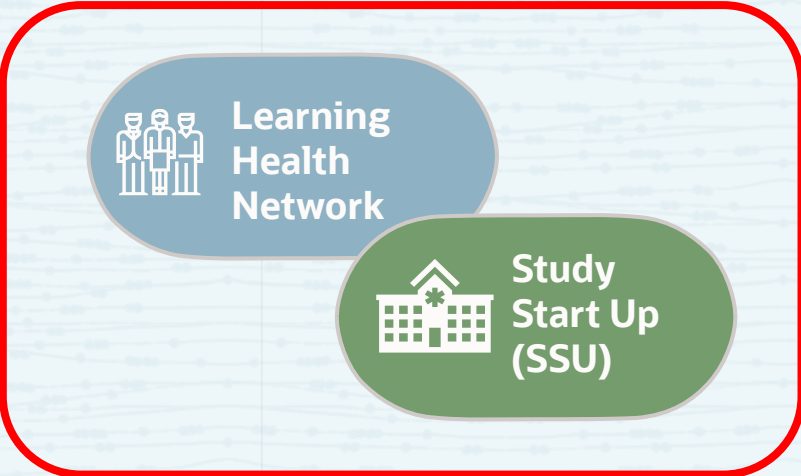
Oracle Life Sciences Innovation Platform

Planning

Startup

Conduct

Analysis & Reporting



Real World Data

Real World Evidence

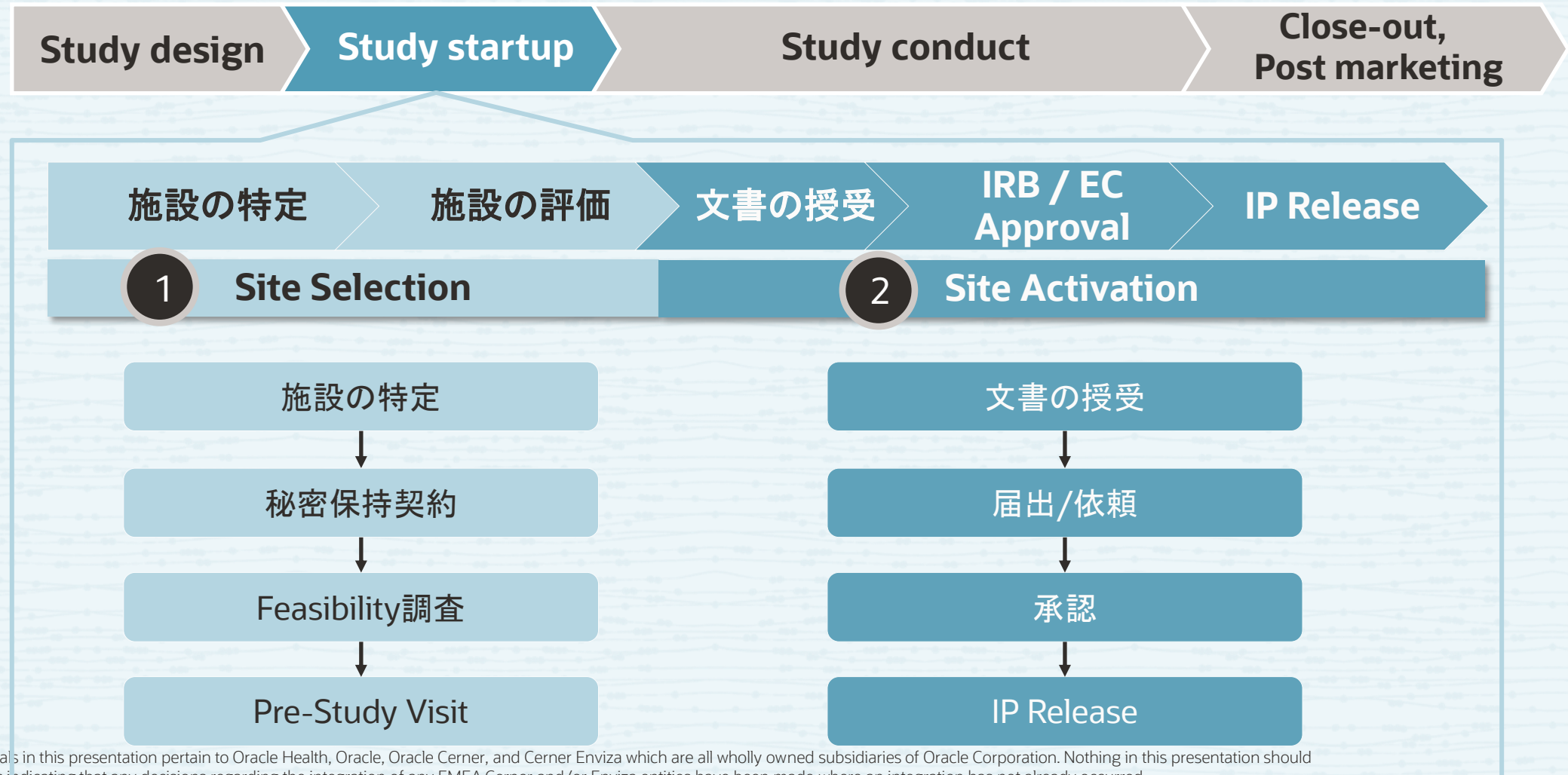
Oracle Cloud Infrastructure

Data Lakehouse | Performance | Security | Scalability | Storage | Useability | AI & ML | Cost Savings

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Study Startupフェーズのプロセス



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Study Start Upに関する数字

site feasibility

11%

non-enrolling sites

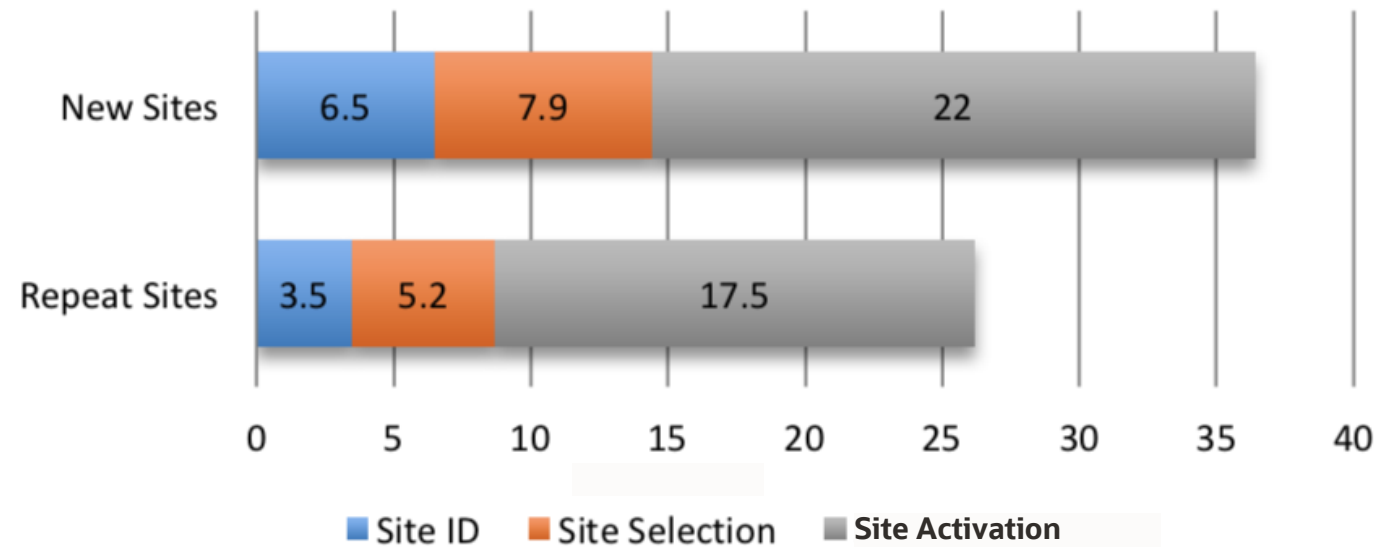
37%

sites under enroll

\$15,000 -
\$30,000

spent on non-active non-enrolling sites

Average Cycle Time Comparisons (Weeks)

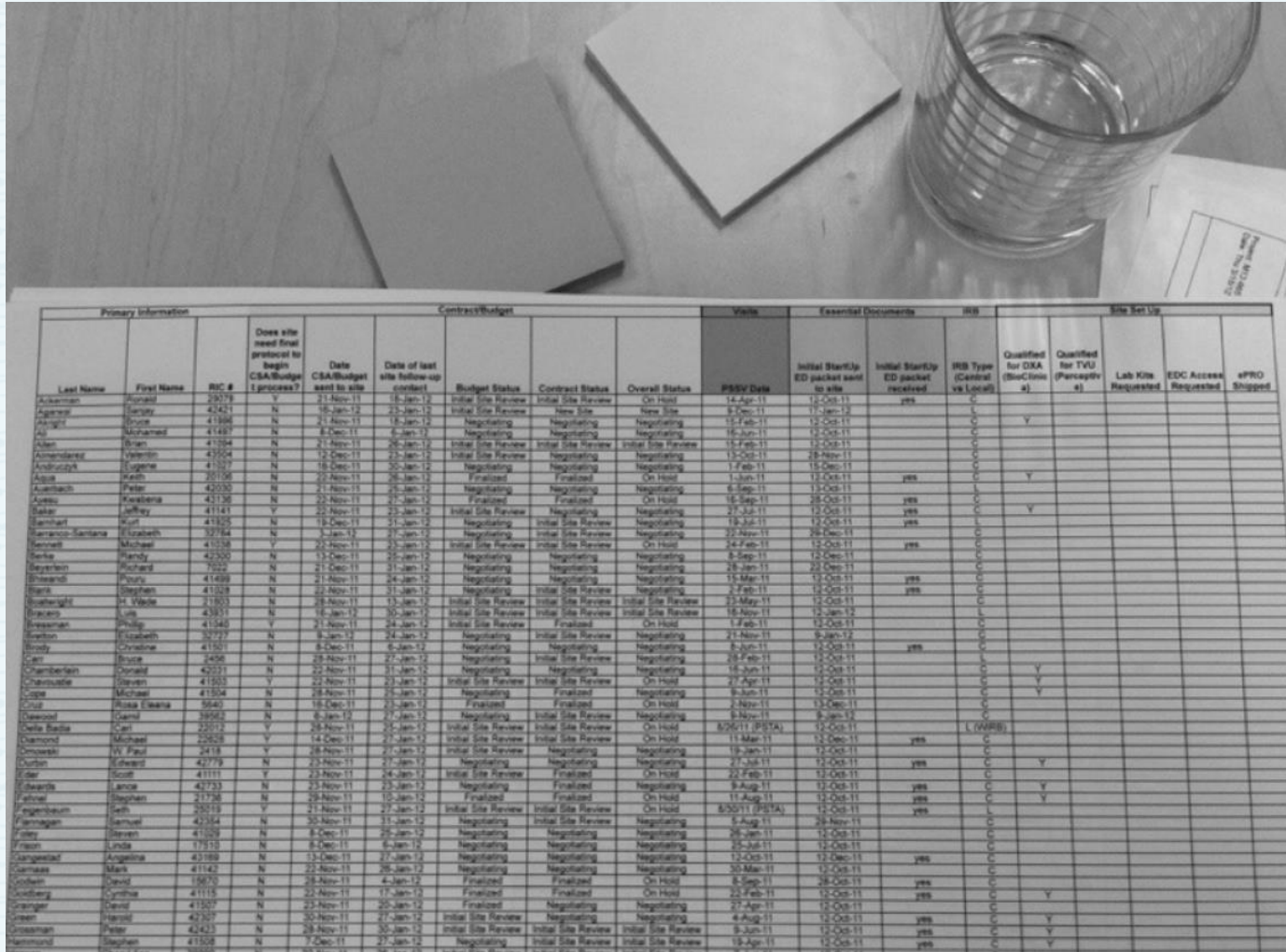


Source: Tufts Center for the Study of Drug Development

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施設選定の現状



Primary Information			Contract/Budget			Value			Essential Documents		SIB		Site Set Up				
Lead Name	First Name	BC #	Does site need final protocol to begin CSA/Budget process?	Date CSA/Budget sent to site	Date of last site follow-up contact	Budget Status	Contract Status	Overall Status	MSB/Date	Initial StartUp ED packet sent to site	Initial StartUp ED packet received	SIB Type (Central vs Local)	Qualified for DXA (BioClinica)	Qualified for TVU (Paracelsus)	Lab Kits Requested	EDC Access Requested	sPRO Shipped
Aschman	Arnold	3275	Y	21-Nov-11	18-Jan-12	Initial Site Review	Initial Site Review	On Hold	14-Apr-11	12-Oct-11	12-Oct-11	C					
Aschman	George	4241	N	16-Jan-12	23-Jan-12	Initial Site Review	Initial Site Review	New Site	8-Dec-11	12-Jan-12	12-Jan-12	C					
Aschman	Brunt	4196	N	21-Nov-11	18-Jan-12	Negotiating	Negotiating	Negotiating	15-Feb-11	12-Oct-11	12-Oct-11	C					
Aschman	Muhammad	41487	N	8-Dec-11	6-Jan-12	Negotiating	Negotiating	Negotiating	16-Jun-11	12-Oct-11	12-Oct-11	C					
Aschman	Oran	41384	N	21-Nov-11	26-Jan-12	Initial Site Review	Initial Site Review	Initial Site Review	15-Feb-11	12-Oct-11	12-Oct-11	C					
Aschman	Yehoshua	43504	N	12-Dec-11	22-Jan-12	Initial Site Review	Negotiating	Negotiating	13-Oct-11	28-Nov-11	28-Nov-11	C					
Andrusch	Eugene	41327	N	18-Dec-11	30-Jan-12	Negotiating	Negotiating	Negotiating	1-Feb-11	15-Dec-11	15-Dec-11	C					
Agar	Wahid	20136	N	22-Nov-11	26-Jan-12	Finalized	Finalized	On Hold	1-Jun-11	12-Oct-11	12-Oct-11	C	Y				
Ashbach	Peter	42033	N	21-Nov-11	25-Jan-12	Negotiating	Negotiating	Negotiating	6-Sep-11	13-Oct-11	13-Oct-11	C					
Akinci	Kwabena	41136	N	30-Nov-11	27-Jan-12	Finalized	Finalized	On Hold	16-Sep-11	26-Oct-11	26-Oct-11	yes					
Baker	Jeffrey	41141	Y	22-Nov-11	23-Jan-12	Initial Site Review	Negotiating	Negotiating	27-Jul-11	12-Oct-11	12-Oct-11	C	Y				
Bambart	Gunn	41825	N	19-Dec-11	31-Jan-12	Negotiating	Initial Site Review	Negotiating	18-Jul-11	12-Oct-11	12-Oct-11	yes					
Baronick-Barana	Elizabeth	32754	N	21-Nov-11	21-Jan-12	Negotiating	Initial Site Review	Negotiating	22-Jan-11	26-Dec-11	26-Dec-11	C					
Baronick	Michael	41558	Y	22-Nov-11	30-Jan-12	Initial Site Review	Initial Site Review	On Hold	24-Feb-11	12-Oct-11	12-Oct-11	yes					
Berke	Randy	42300	N	13-Dec-11	25-Jan-12	Negotiating	Negotiating	Negotiating	8-Sep-11	12-Dec-11	12-Dec-11	C					
Beitman	Richard	7222	N	21-Dec-11	31-Jan-12	Negotiating	Negotiating	Negotiating	26-Jan-11	22-Dec-11	22-Dec-11	C					
Berens	Henry	41488	N	21-Nov-11	30-Jan-12	Negotiating	Negotiating	Negotiating	13-Mar-11	13-Oct-11	13-Oct-11	yes					
Berns	Stephen	41028	N	22-Nov-11	31-Jan-12	Negotiating	Initial Site Review	Negotiating	2-Feb-11	12-Oct-11	12-Oct-11	yes					
Bushright	H. Wade	21803	N	28-Nov-11	13-Jan-12	Initial Site Review	Initial Site Review	Initial Site Review	23-May-11	12-Oct-11	12-Oct-11	C					
Braico	Luca	43851	N	16-Jan-12	30-Jan-12	Initial Site Review	Initial Site Review	Initial Site Review	16-Nov-11	12-Jan-12	12-Jan-12	L					
Bresnan	Paul	41548	Y	21-Nov-11	30-Jan-12	Initial Site Review	Finalized	On Hold	1-Feb-11	12-Oct-11	12-Oct-11	C					
Brown	Elizabeth	30777	N	8-Jan-12	24-Jan-12	Negotiating	Initial Site Review	Negotiating	23-Nov-11	8-Jan-12	8-Jan-12	C					
Bundy	Christine	41501	N	8-Dec-11	6-Jan-12	Negotiating	Negotiating	Negotiating	8-Jun-11	12-Oct-11	12-Oct-11	yes					
Can	Bruce	2456	N	28-Nov-11	27-Jan-12	Negotiating	Initial Site Review	Negotiating	28-Feb-11	12-Oct-11	12-Oct-11	L		Y			
Chamberlain	Donald	42211	N	22-Nov-11	31-Jan-12	Negotiating	Negotiating	Negotiating	18-Jun-11	12-Oct-11	12-Oct-11	C					
Chaturvedi	Deepan	41541	Y	21-Nov-11	30-Jan-12	Initial Site Review	Initial Site Review	On Hold	2-Apr-11	12-Oct-11	12-Oct-11	C		Y			
Coyle	Michael	41504	N	28-Nov-11	29-Jan-12	Negotiating	Negotiating	Negotiating	9-Jun-11	12-Oct-11	12-Oct-11	C					
Crut	Rosa Elena	5640	N	18-Dec-11	23-Jan-12	Finalized	Finalized	On Hold	7-Nov-11	13-Dec-11	13-Dec-11	C					
Dawson	Dani	38982	N	6-Jan-12	27-Jan-12	Negotiating	Initial Site Review	Negotiating	1-Nov-11	8-Jan-12	8-Jan-12	C					
DeLaBelle	Carl	22573	N	8-Dec-11	26-Jan-12	Initial Site Review	Initial Site Review	On Hold	5/2011 (PITA)	12-Oct-11	12-Oct-11	L (WFR)					
Demond	Michael	25252	Y	14-Dec-11	29-Jan-12	Initial Site Review	Initial Site Review	On Hold	11-Mar-11	12-Dec-11	12-Dec-11	yes					
Dinesh	W. Paul	2418	Y	28-Nov-11	27-Jan-12	Initial Site Review	Negotiating	Negotiating	19-Jan-11	12-Oct-11	12-Oct-11	C					
Durban	Edward	42779	N	23-Nov-11	27-Jan-12	Negotiating	Negotiating	Negotiating	27-Jul-11	12-Oct-11	12-Oct-11	yes		Y			
Eber	Scott	41111	Y	23-Nov-11	24-Jan-12	Initial Site Review	Finalized	On Hold	22-Feb-11	12-Oct-11	12-Oct-11	C		Y			
Edwards	Leopold	42753	N	23-Nov-11	23-Jan-12	Negotiating	Negotiating	Negotiating	9-Aug-11	12-Oct-11	12-Oct-11	yes		Y			
Elmer	Stephen	21738	N	28-Nov-11	10-Jan-12	Finalized	Finalized	On Hold	11-Aug-11	12-Oct-11	12-Oct-11	yes		Y			
Eugenbaum	Seh	20219	Y	21-Nov-11	27-Jan-12	Initial Site Review	Initial Site Review	On Hold	6/2011 (PITA)	12-Oct-11	12-Oct-11	yes					
Farrington	Samuel	42334	N	30-Nov-11	31-Jan-12	Negotiating	Initial Site Review	Negotiating	5-Aug-11	26-Nov-11	26-Nov-11	C					
Felix	Seveth	41028	N	8-Dec-11	26-Jan-12	Negotiating	Negotiating	Negotiating	26-Jun-11	12-Oct-11	12-Oct-11	C					
Fisher	Linda	11512	N	8-Dec-11	6-Jan-12	Negotiating	Negotiating	Negotiating	12-Jul-11	12-Oct-11	12-Oct-11	C					
Fingstad	Angeline	43789	N	13-Dec-11	27-Jan-12	Negotiating	Negotiating	Negotiating	12-Oct-11	12-Dec-11	12-Dec-11	yes					
Fontana	Mark	41142	N	22-Nov-11	26-Jan-12	Negotiating	Negotiating	Negotiating	30-Mar-11	12-Oct-11	12-Oct-11	C					
Gooden	Dani	19870	N	28-Nov-11	4-Jan-12	Finalized	Finalized	On Hold	8-Sep-11	26-Oct-11	26-Oct-11	yes					
Gooding	Carlyne	41113	N	23-Nov-11	17-Jan-12	Finalized	Finalized	On Hold	23-Feb-11	12-Oct-11	12-Oct-11	yes		Y			
Granger	Edward	41202	N	23-Nov-11	30-Jan-12	Finalized	Negotiating	Negotiating	27-Apr-11	12-Oct-11	12-Oct-11	C					
Gross	Harold	42327	N	30-Nov-11	27-Jan-12	Initial Site Review	Negotiating	Negotiating	4-Aug-11	12-Oct-11	12-Oct-11	yes		Y			
Grossman	Peter	42423	N	28-Nov-11	30-Jan-12	Initial Site Review	Initial Site Review	Initial Site Review	9-Jun-11	12-Oct-11	12-Oct-11	C		Y			
Hammond	Stephen	41508	N	7-Dec-11	27-Jan-12	Negotiating	Initial Site Review	Initial Site Review	19-Apr-11	12-Oct-11	12-Oct-11	yes		Y			
Hartman	Robert	30525	N	18-Nov-11	16-Jan-12	Initial Site Review	Initial Site Review	On Hold	1-Feb-11	12-Oct-11	12-Oct-11	C					

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Study Start Up（施設選定）における課題

どこに専門家がいるかわからない...



施設選定に客観性がない...



メールや手作業での進捗管理...
プロセスがアナログ



プロセスが標準化されておらず属人的

プロジェクトマネジメントしろと言われても...



脱メール・脱エクセル・脱ミーティング

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ion should



候補施設のノミネートと施設パフォーマンスのスコア化

select account setup manage nominate evaluate select finalize dashboards Akira Soma AS ?

Study: PURW_888 Status: In setup Protocol: PW-2309-2020

Nominate sites to invite 1 Collaborate on the feasibility evaluation of sites. 2 Select sites to accept for study. Surveys: 47/100 3 Finalize site selected and decline lists. 4

Master list Review (28) Dropped (12)

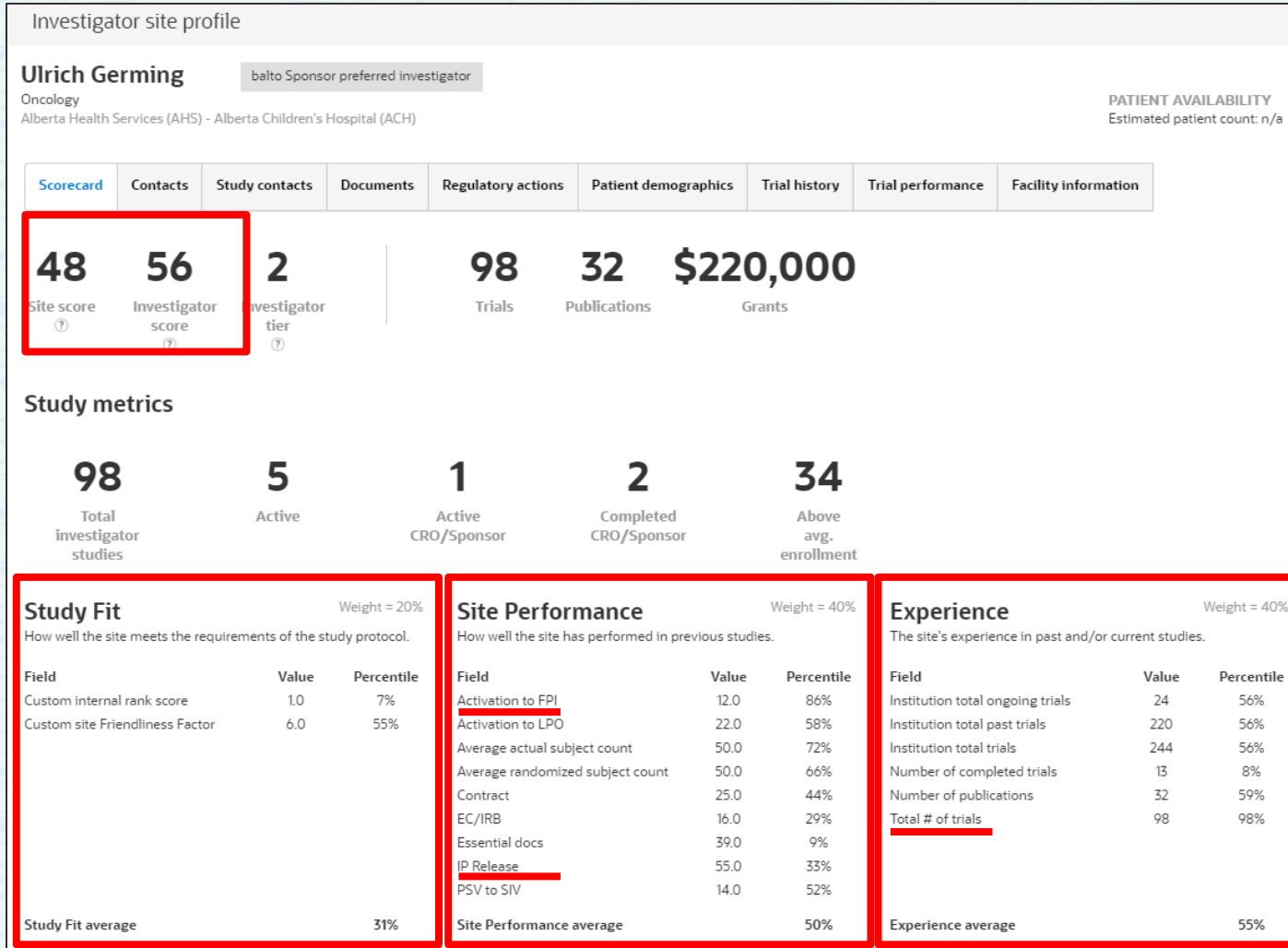
施設スコア 医師スコア Search Investigators Sites Trials 1 - 50 of 55

	SITE SCORE	INVESTIGATOR SCORE	SITE PROFILE	NOTES	INVESTIGATOR	INSTITUTION	COUNTRY	ACTIONS
<input type="checkbox"/>	45	53			Cervantes Ruiperez, Andres	British Columbia Cancer Agency (BCCA) - The Vancouver Centre	Canada	
<input type="checkbox"/>	45	51			Geden, Chris	IWK Health Centre - Main Location	Canada	
<input type="checkbox"/>	45	54			Germing, Ulrich	Alberta Health Services (AHS) - Alberta Children's Hospital (ACH)	Canada	
<input type="checkbox"/>	45	46			Donald, Nick	Herridge Community Health Clinic	Canada	
<input type="checkbox"/>	45 *	47			Santillana, Gloria	Shriners Hospital for Children	Canada	

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施設パフォーマンスのスコア化



- 施設スコアの詳細を表示
- システムに取り込まれたデータに基づいて項目毎に施設をランク付け
- それぞれの個別スコアの加重平均で施設スコアを算出

例

Study Fit (Weight = 20%): 31%
 Site Performance (Weight = 40%): 50%
 Experience (Weight = 40%): 55%
 の場合

$$(31*0.2 + 50*0.4 + 55*0.4)/3=48$$

施設スコア: Investigatorが所属する施設が保有しているスコア
 医師スコア: 複数のSiteに所属している場合その平均値



施設への打診



[External] : New research study opportunity

akira.soma@oracle.com
To Akira Soma

患者様にとって興味深いと思われる臨床試験についてお知らせし、参加を検討していただきたいと思います。

貴施設の診療所でこの試験への参加に興味のある潜在的な患者様とお話できることを楽しみにしています。ご質問がございましたら、下記の連絡先までお気軽にお問い合わせください。

あなたの時間と配慮していただきありがとうございます。

I would like to let you know about a research study that may be of interest to your patients and ask you to consider participation.

We look forward to speaking with you regarding potential patients in your practice who may be interested in participating in this study. Please feel free to contact me with questions using the contact information provided below.

Thank you for your time and consideration.

There are two ways to access the study management tool:

No log in required	Log in required
<ul style="list-style-type: none">• Don't need to remember password• Secured access via encrypted link	<ul style="list-style-type: none">• Able to access at any time• Access to document library• Create a site profile and gain access to additional studies• Faster communication with CRO/sponsor



select LITE communications document library site details Logged in as guest

IWK Health Centre - Main Location

Study: PURW_888 — Chris Geden Feasibility tasks must be completed by 28Feb2024.

Your study workflow tasks

Completed	Completed - external	Pending review	Discontinued	Incomplete
0	0	0	0	5

Verify site profile information

Task name: Verify site profile information

Task information: if your profile is already filled out please only edit that are incorrect or have changed.

Task age: 1 day

Task actions: [Verify site profile information](#)

home support news room privacy policy terms of service about Oracle Health Sciences © 2015-2024 Oracle version 23.3



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候補施設の選定

Study: PURW_888 | Status: In setup | Protocol: PW-2309-2020 | The default workflow closes on 28Feb2024.

1. Nominate sites to invite | 2. Collaborate on the feasibility evaluation of sites. | 3. Select sites to accept for study. Surveys: 47/101 | 4. Finalize site selected and decline lists.

Invited (68) | Recommended (0) | Selected (6) | Back up (2) | Not Interested (2) | Declined (2)

Search

Site progress | Survey analysis | Site details

施設の対応状況・進捗状況を把握することが可能です

	INVESTIGATOR	COUNTRY	INVIT. RCVD.	ACCESS SELECT LITE	SET WORKFLOW	VERIFY SITE ...	SIGN AND RET...	VIEW PROTOCOL	VERIFY SITE ...	COMPLETE FEA...	ASKS ONE?	INTERESTED SITE	DISINT. REASONS	WORKFLOW C DATE	ACTIONS
<input checked="" type="checkbox"/>	Geden, Chris	Canada	✓	✓	General Site Workflow	✓	—	—	—	—	No	-	📄	28Feb2024	✎
<input type="checkbox"/>	Cervantes Ruiperez, Andres	Thailand	✓	✓	General Site Workflow	✓	⚠	—	—	—	No	-	📄	28Feb2024	✎
<input type="checkbox"/>	McGregor, Ewan	Canada	✓	✓	General Site Workflow	✓	✓	✓	✓	✓	Yes	Yes	📄	28Feb2024	✎
<input type="checkbox"/>	Mohan, Sandeep	Germany	✓	✓	General Site Workflow	✓	✓	✓	✓	✓	Yes	Yes	📄	28Feb2024	✎

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Study Milestone Prediction

activate

Plan study +

Studies

Set up

← go back
Study: TEST0404
Save and Exit

Tabular
Dashboard

50%

Select Countries

Export to CSV ?

Save

Prediction		Study summary milestones										
Therapeutic Area	Study & Planned sites	First Contract Indemnity	50% Contract Indemnity	First IP Release	50% IP Release	First SIV	50% SIV	90% Contract Indemnity	Last Contract Indemnity	90% IP Release	Last IP Release	90% SIV
Immunology	TEST0404 60	15SEP2024	15SEP2024	26SEP2024	29SEP2024	01OCT2024	04OCT2024	01DEC2024	01DEC2024	10DEC2024	10DEC2024	15DEC2024

Prediction		Provided milestones	Country summary milestones									
Country & Planned sites	Final Approved Protocol	First Contract Indemnity	First IP Release	First SIV	50% Contract Indemnity	50% IP Release	50% SIV	90% Contract Indemnity	90% IP Release	90% SIV	Last Contract Indemnity	Last IP Release
Canada 10	04APR2024	19SEP2024	26SEP2024	01OCT2024	19SEP2024	26SEP2024	01OCT2024	04OCT2024	11OCT2024	16OCT2024	04OCT2024	11OCT2024
Japan 20	04APR2024	12NOV2024	19NOV2024	24NOV2024	14NOV2024	21NOV2024	26NOV2024	01DEC2024	10DEC2024	15DEC2024	01DEC2024	10DEC2024
United States 30	04APR2024	15SEP2024	29SEP2024	04OCT2024	15SEP2024	29SEP2024	04OCT2024	15SEP2024	29SEP2024	04OCT2024	15SEP2024	29SEP2024

※他社も含めたOracle SSUユーザーの平均からMilestone達成時期を予測

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The Insights

Oracle Learning Health Network

The 114* LHN members represent >32,000 hospital beds and 2,542 facilities in 44 states + Washington, D.C.

LHN member health system care settings



- Independent Pediatric Health System (5)
- Critical Access Hospital (56)
- IDN (24)
- Short Term Acute Care Hospital (27)
- Physician/Clinic Group (2)

*LHN member data current as of 07/30/2023.

¹Urban/Rural designation derived from cms.gov data source from 2015Q4

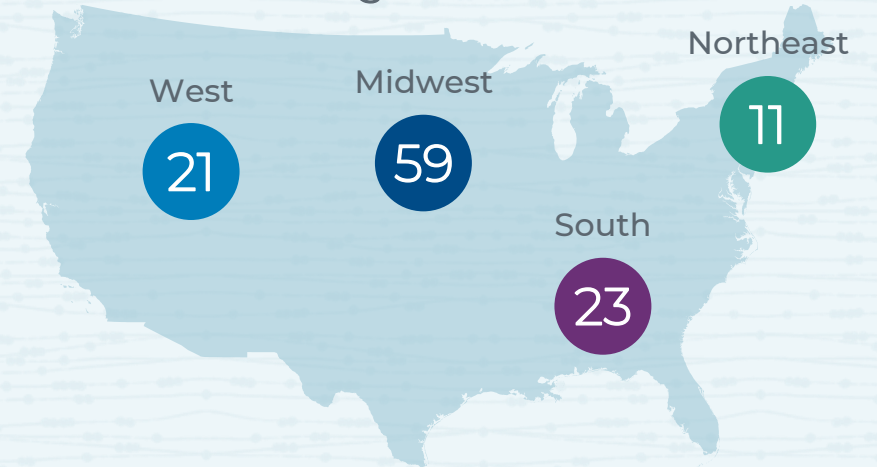


Current clinical trials?

Yes: 48

No: 66

Region count



Data contributor extraction



Data cleansing

Concept normalization

Data standardization

Person matching

De-identification



Data mart creation



Real-World Data access



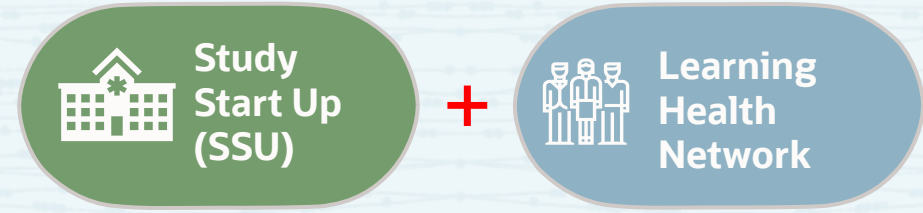
Run feasibility queries across 103M patients to identify potential study sites

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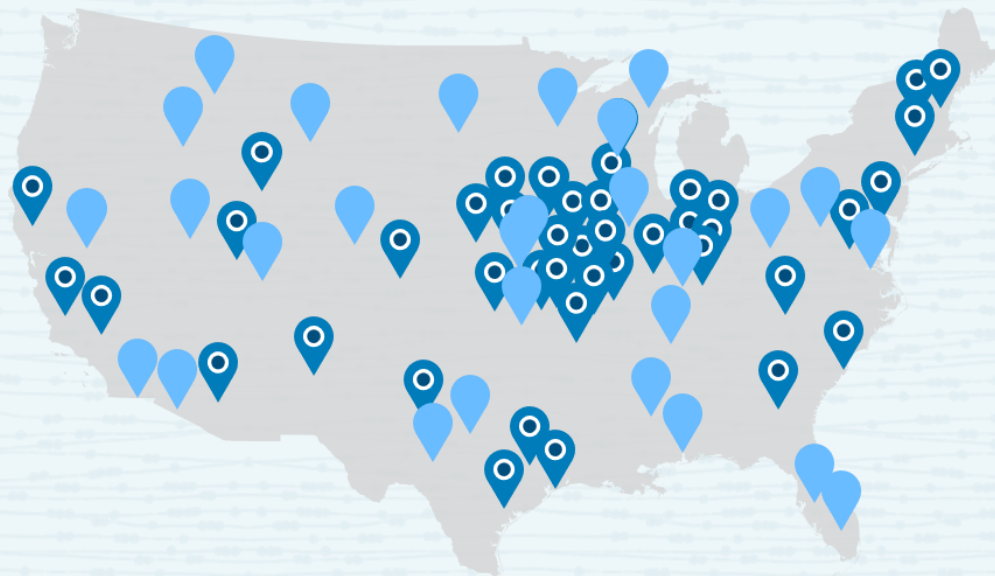


The Solution

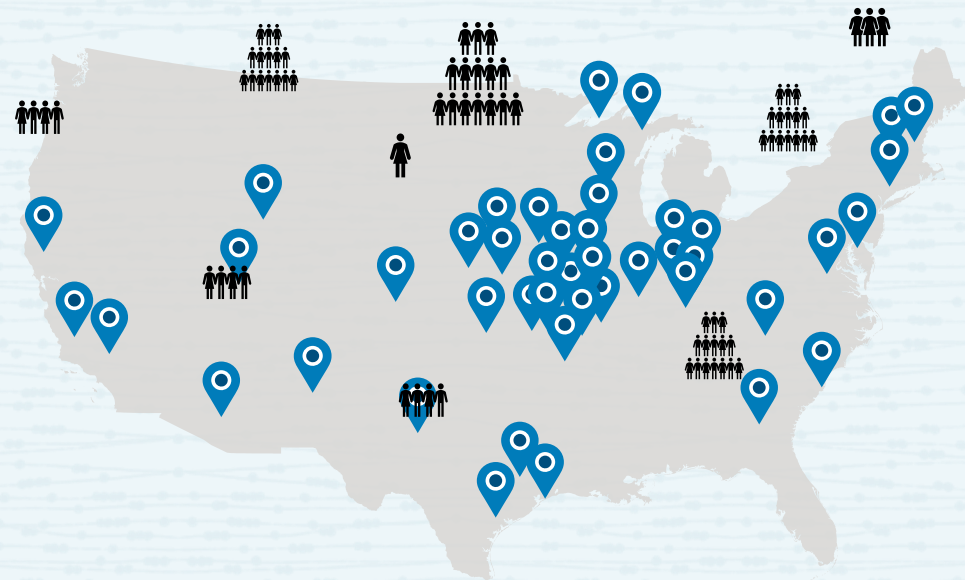
Oracle Study Startup Solutions + LHN



Crosswalk LHN sites with Sponsor and/or CRO's sites



Surface patient feasibility counts for overlapping sites based on RWD



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Account: Standard Account Study: LHN study demo Status: Active Protocol: OCT-1008



Master list Review (1) Dropped (0)

Add to review Search

Learning Health Network last update: 15Apr2024 11:08 AM by Jonathan Lofton

<input type="checkbox"/>	PREFERRED SITE	SITE SCORE	SITE PROFILE	NOTES	INVESTIGATOR	INSTITUTION	LHN COUNT OF MATCHING PATIENTS	COUNTRY	ACTIONS
<input checked="" type="checkbox"/>		0			Baqir, Misbah	Mayo Clinic	205	United States	
<input type="checkbox"/>		0			Hresvelg, Edelgard	Cedars-Sinai Medical Center	194	United States	
<input checked="" type="checkbox"/>		0			Bai, Chunxue	Shanghai Zhongshan Hospital	118	United States	
<input checked="" type="checkbox"/>		0			Lidsky, Michael	Duke University	74	United States	
<input type="checkbox"/>		0			Kraft, Monica	Duke University	74	United States	
<input type="checkbox"/>	☆	0			Curtis, Lesley	Duke University	74	United States	
<input type="checkbox"/>		0			Beichel, Reinhard	University of Iowa	56	United States	
<input type="checkbox"/>		0			Baker, Kimberly	University of Iowa	56	United States	
<input type="checkbox"/>		0			El Zein, Randa	Methodist Hospital Research Institut	55	United States	
<input type="checkbox"/>		0			Benninger, Michael	The Cleveland Clinic	52	United States	
<input type="checkbox"/>		0			Brockbank, Kelvin	The Cleveland Clinic	52	United States	
<input type="checkbox"/>		0			Parks, William	The Cleveland Clinic	52	United States	
<input type="checkbox"/>		0			Know, Kenneth	The Cleveland Clinic	52	United States	

* Not all site responses were available for calculating this score.

The ma
be taker





[Back to Studies](#)

[Edit Study](#)

Comparative Analysis of Asthmatic Cough Patient Treatment

Available Patients
641

Eligible
101

Chart Review
89

In Follow-Up
174

Enrolled
111

Ineligible
41

Declined
67

🔍 Search...

Status **In Follow-Up 174**

Last Seen At **AU Main Theatre**

Name	Status	Last Seen At	Next Appointment Date	Eligibility ↑	Actions
Emma Barr	Chart Review	BW Lab	April 13, 2024	75%	Actions ▾
Victoria Agbayani	Declined	RC Family Pract	April 19, 2024	75%	Actions ▾
Louisa Park	Eligible	RC Urgent Care	April 14, 2024	75%	Actions ▾
Madeline Poubelle	Eligible	BW Med Onc Clin	April 19, 2024	75%	Actions ▾
Girish Gupta	Ineligible	BW Summit	April 19, 2024	75%	Actions ▾

Diversity Action Plans Will Soon Be Mandatory for Clinical Trials

Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to <https://www.regulations.gov>. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact (OCE) Lola Fashoyin-Aje, 240-402-0205, (CDER) Tamy Kim 301-796-1125, (CBER) Office of Communication, Outreach, and Development, 800-835-4709, or 240-402-8010, or (CDRH), CDRH Clinical Evidence Mailbox, CDRHClinicalEvidence@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Oncology Center of Excellence (OCE)
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)
Office of Minority Health and Health Equity (OMHHE)
Office of Women's Health (OWH)

June 2024
Clinical/Medical

- もうすぐ義務化
- IND時（遅くともEnd of Phase IIまで）にRace & Ethnicity Diversity Planを提出する
- 含めるべき内容
 - 年齢層、性別、Race、Ethnicityごとに分類された登録目標
 - 登録目標に対する理論的根拠
 - 登録目標をどう達成するか計画（被験者登録の戦略、Inclusion & Exclusion practice、試験関係者へのDiversity トレーニング等）
- 業界へのインパクト
 - 登録状況のリアルタイムモニタリング
 - Black、Asian、Hispanicの被験者の奪い合い
 - 新たな国/地域での被験者Recruitment、施設立ち上げ

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Transforming Clinical Research

Oracle Study Start Upの生み出す価値

Quality of Data

- 客観性のある施設選定
- 手作業削減によるデータ品質の向上
- ボトルネックの早期特定による試験品質の向上

Speed

- リアルタイムでの進捗状況の把握・意思決定
- アナログプロセスからの脱却によるスピードアップ
- 手作業の削減によるスピードアップ

Cost

- 作業工数削減
- 試験の早期立ち上げによる機会利益*

*機会利益：同じ期間で最も利益を生み出す選択肢と他の選択肢との利益の差

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Thank you

akira.soma@oracle.com

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