

Clinical Research Access and
Information Exchange Initiative

eBook:

CLINICAL TRIAL REGISTRY OF THE FUTURE

Patient-Focused Features
Proposed for Consideration
by Public Registries



TransCelerate
BIOPHARMA INC.

ACCELERATING THE DEVELOPMENT OF NEW MEDICINES

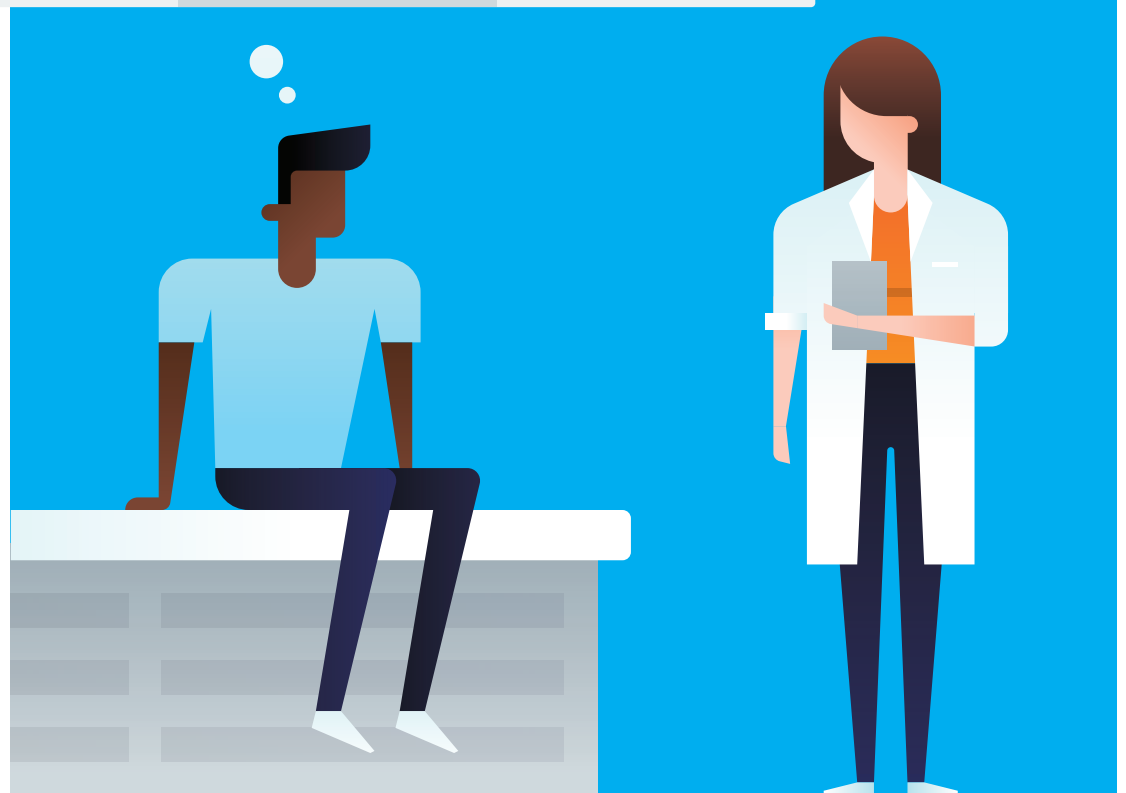
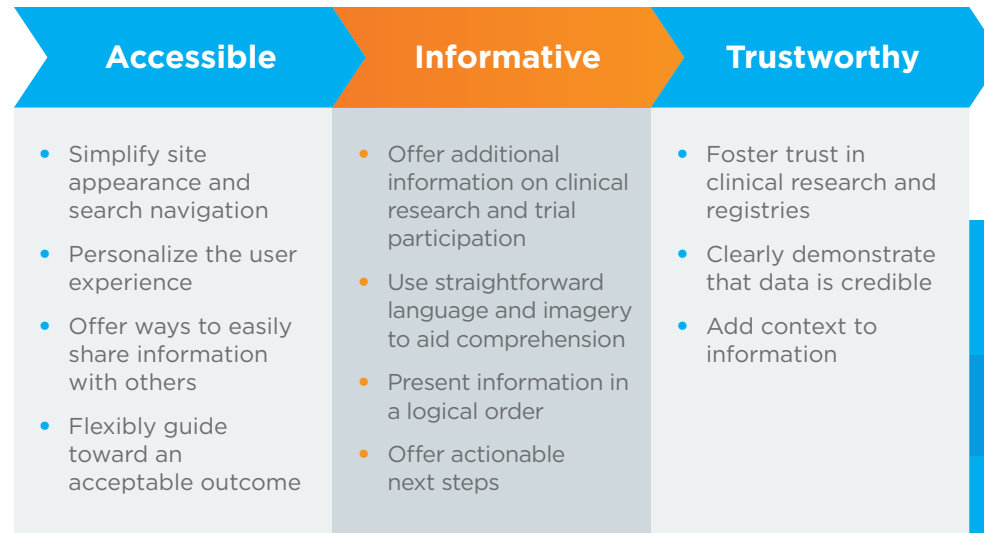
» BEGINNING WITH THE PATIENT IN MIND

Beginning in 2016, TransCelerate sought the input of a diverse group of patients on information desired about clinical trials, the user experience of existing public registries and improvement opportunities for future public registry design. Through consultation and collaboration with patients, key takeaways pertaining to the design of a “Clinical Trial Registry of the Future” concept were summarized into three categories:

- Accessible
- Informative
- Trustworthy

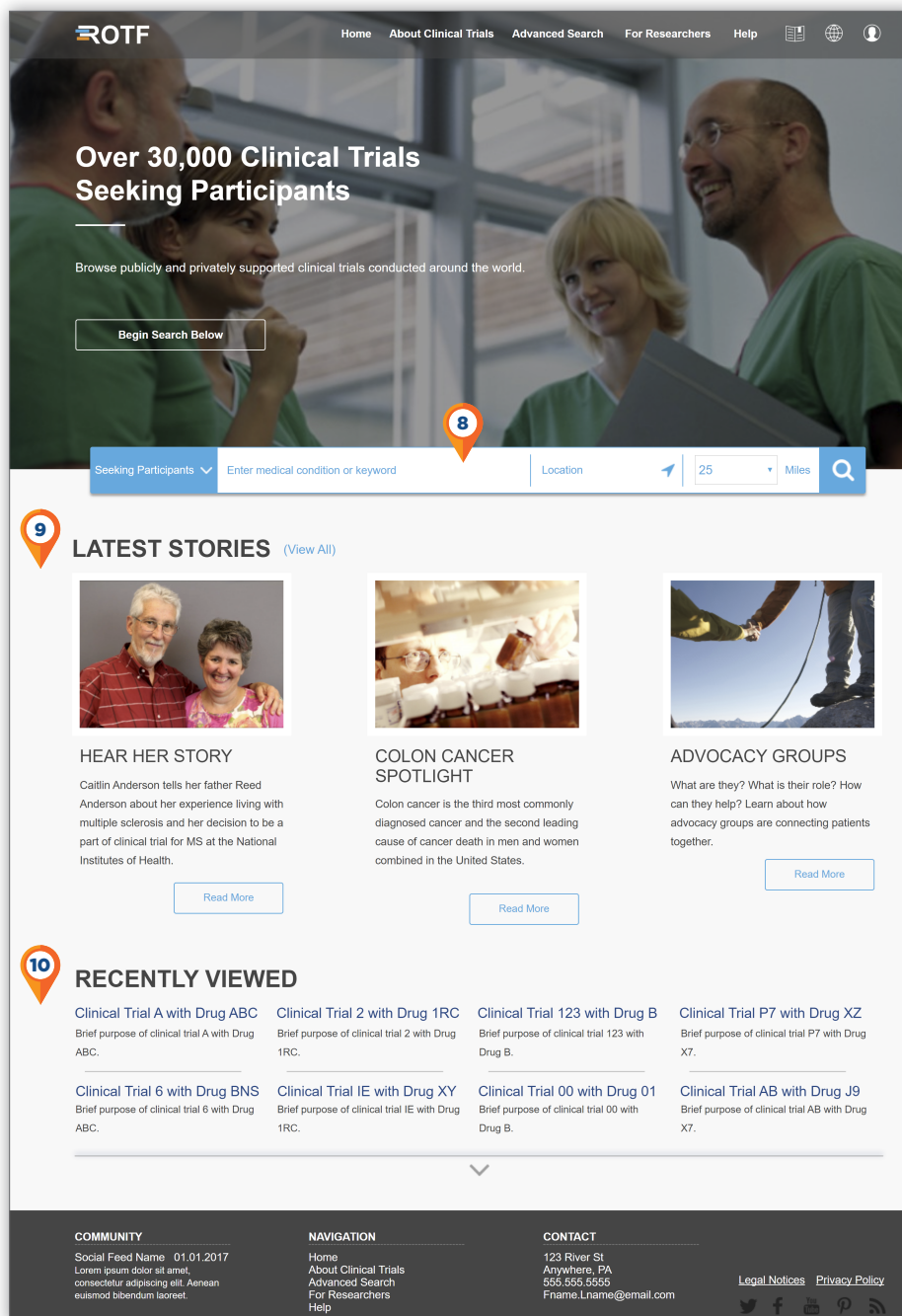
GUIDING PRINCIPLES FOR CLINICAL TRIAL REGISTRY DESIGN

It is with these guiding principles in mind that future efforts to enhance, improve or extend the utility of public clinical trial registries should be taken. In order to explore specific features or enhancements which satisfy the above principles, and to initiate broad multi-stakeholder discussion on practical advances toward these goals, TransCelerate co-designed with patients a wireframe proof of concept for “Clinical Trial Registry of the Future.”



CLINICAL TRIAL REGISTRY OF THE FUTURE WIREFRAME HOMEPAGE

Focusing on the desktop user experience as a starting point, the homepage for Clinical Trial Registry of the Future was designed to welcome users into a positive environment and facilitate easy searching of clinical trial information.



- About Clinical Trials:** educational content about clinical trials that answers seven commonly asked questions.
- Advanced Search:** access to all possible search criteria from a single page for more advanced users.
- For Researchers:** resource hub for researchers and study record managers including guidance on registration.
- Help:** resource hub for users containing FAQs, glossary of terms, clinical trial education library and tutorials for use of the platform.
- Bookmarks:** access to content previously saved by user for future reference.
- Language Preferences (Globe):** drop-down to select appropriate language/region preference to personalize display (e.g. kilometers versus miles).
- User Account:** access to and/or option to create a personal account enabling additional features and saved preferences.
- Simple Search:** search for trials in three basic categories (seeking participants, completed with results, or all trials) by keyword or condition, with option to specify a base location and radius within which to search. "Smart" features are built in to allow detection of current location, if desired, and type-ahead functionality which automatically pulls suggested search terms as user begins typing.
- Latest Stories:** content of interest to various patient and disease communities, dynamically displayed based on user's browse/search history.
- Recently Viewed:** easy access to clinical trials recently viewed by the user.

SEARCH RESULTS

The trial search results page provides a comprehensive view of important trial characteristics while allowing the user flexibility to customize additional filter criteria, plot results on a map, build a side-by-side comparison, or take additional actions on specific trial listings.

Disclaimer: This interactive wireframe was designed by TransCelerate BioPharma for use in demonstrations to regulatory authorities. [Read More >](#)

ROTF Home About Clinical Trials Advanced Search For Researchers Help

Home > Search Results

Colorectal Cancer Philadelphia, PA (19125)

We have found 22 matching trials [Help me refine my results](#)

Condition: Colorectal Cancer Distance: 25 miles Location: Philadelphia, PA (19125) Status: Seeking Participants

Grid View Map View

6 FILTER BY Showing: 1 - 10 of 22 trials Trials per page: 10

Status **1**

Trials:

☐ Seeking Participants

☐ Completed with Results

☐ All

Advanced **2**

Distance **3**

19125 25 +

Condition **4**

Trial Type **5**

Trial Phase **6**

Intervention **7**

Time Commitment **8**

Placebo Possible **9**

Age & Sex **10**

Accepts Healthy Volunteers **11**

Funder Type **12**

Trial Results **13**

Hidden Trials **14**

NAME	CONDITION	INTERVENTION	DISTANCE	COMMITMENT	STATUS	ACTIONS
<input type="checkbox"/> A study of Drug ABC in patients with advanced solid tumors	Colorectal Cancer, Colon Cancer	Drug ABC	12 Mi	Months 6 +/- Visits 15 +/-	Seeking Participants	
<input type="checkbox"/> A study of Drug 1RX in patients with advanced solid tumors	Colon Cancer	Drug 1RX	13 Mi	Months 4 +/- Visits 18 +/-	Seeking Participants	
<input type="checkbox"/> A study of Treatment 123 in patients with advanced solid tumors	Colorectal Cancer	Procedure 123	15 Mi	Months 5 +/- Visits 14 +/-	Seeking Participants	
<input type="checkbox"/> A study of Drug AUB in patients with advanced solid tumors	Colon Cancer	Drug AUB	16 Mi	Months 8 +/- Visits 23 +/-	Seeking Participants	
<input type="checkbox"/> A study of Treatment P&R in patients with advanced solid tumors	Colorectal Cancer, Colon Cancer	Procedure P&R	17 Mi	Months 6 +/- Visits 17 +/-	Seeking Participants	
<input type="checkbox"/> A study of Drug 2WO in patients with advanced solid tumors	Colon Cancer	Drug 2WO	18 Mi	Months 18 +/- Visits 38 +/-	Seeking Participants	
<input type="checkbox"/> A study of Drug WWW in patients with advanced solid tumors	Colorectal Cancer	Drug WWW	18 Mi	Months 5 +/- Visits 10 +/-	Seeking Participants	
<input type="checkbox"/> A study of Drug 000 in patients with advanced solid tumors	Colorectal Cancer	Drug 000	20 Mi	Months 5 +/- Visits 16 +/-	Seeking Participants	
<input type="checkbox"/> A study of Drug CBA in patients with advanced solid tumors	Colorectal Cancer, Colon Cancer	Drug CBA	23 Mi	Months 14 +/- Visits 31 +/-	Seeking Participants	
<input type="checkbox"/> A study of Drug X in patients with advanced solid tumors	Colorectal Cancer, Colon Cancer	Drug X	25 Mi	Months 4 +/- Visits 13 +/-	Seeking Participants	

7 Compare Selected

< 1 2 3 >

6. Filter Pane: manually refine results based on additional trial attributes or trial participant preferences, including intervention type, estimated participant time commitment and condition-specific factors (e.g. molecular profile of tumor). Hover over filter categories and individual criteria to reveal glossary-supported term definitions.

7. Compare Selected: after ticking checkboxes for each desired trial listing, users may generate a side-by-side comparison of selected trials containing all attributes on the filter pane as well as select non-structured (e.g. free text) trial attributes. The comparison table may be downloaded, printed or shared via email directly from the page.

- 1. Search Criteria:** view confirms previously entered search criteria and provides option to 'x' out of criteria the user no longer wishes to include.
- 2. Help Me Refine My Results:** open a guided search pop-up window for users wishing to answer a series of optional questions about the chosen condition and/or prospective trial participant.
- 3. Search Results Action Buttons:** bookmark the chosen search criteria to re-visit results at a later date, set an alert to be automatically notified of new results under the same search criteria, and download, print, or share the results table.
- 4. Map View:** alternative to grid view which plots all results on a single geographic map with zoom-in and drill-down capability.
- 5. Search Results Grid:** view key attributes of each trial, including intervention category (indicated by icon) and intervention name, distance from desired search location with hover-over capability to reveal location name, and estimated trial participant commitment in total duration and number of visits. Action buttons for each individual trial listing in the grid allow users to bookmark a single trial for future reference, track trials of specific interest, record or open previously written notes about the trial, or hide a trial from view. Gold bars indicate new trials posted since the user's last visit.

» SEARCH RESULTS (OPTIONS), *continued*

“No Results Available” »

Disclaimer: This interactive wireframe was designed by TransCelerate BioPharma for use in demonstrations to regulatory authorities. [Read More >](#)

Home > Search Results

Colorectal Cancer Altoona, PA (16601) 🔍

We have found 4 matching trials [Help me refine my results](#) +

Condition: Colorectal Cancer x Distance: 250 miles x Location: Altoona, PA (16601) x Status: Seeking Participants x

Grid View Map View

No results matched your criteria exactly.

We have found no results that match your search criteria. Please see below for tips & suggestions on ways to improve results that may interest you. If you would like to create an alert for when results are available, [sign in](#) or [register](#).

We have expanded your search radius to **250 miles** from Altoona, PA (16601) instead of 25 miles. You will now see **4 Trials**.

You could also try

[Change search location >](#)

[Change search radius >](#)

[Search another medical condition or keyword >](#)

[Go Back](#) [Continue](#)

Additional Resources

NAME	TYPE	LINK
Group XYZ	Advocacy Group	www.GroupXYZ.com
Group ABC	Advocacy Group	www.Group-ABC.com
Group 123	Advocacy Group	www.Group-123.com
WebSource ABC	Informational	www.WebSourceABC.org
LMNOP Group	Patient Support	www.LMNOP-Group.com

Funder Type ⓘ +

Trial Results ⓘ +

Hidden Trials ⓘ +

“Help Me Refine My Results” »

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Home > Search Results

Colorectal Cancer Philadelphia, PA (19125) 🔍

We have found 22 matching trials [Help me refine my results](#) +

Condition: Colorectal Cancer x Distance: 25 miles x Location: Philadelphia, PA (19125) x Status: Seeking Participants x

Grid View Map View

Refine your search results

Answer a few *optional* questions to better refine your search results. These are to help get you started. You can always modify them at any time from the filters on the left-hand side of the search results page or by simply returning to this page.

● ○ ○ ○ ○ ○ View 22 Results

What is your medical condition or diagnosis?

Colorectal Cancer

[NEXT](#)

Funder Type ⓘ +

Trial Results ⓘ +

Hidden Trials ⓘ +

Some results

A study of Drug WWW in patients with advanced solid tumors Colorectal Cancer Drug WWW 18 M Months 5 +/- Visits 10 +/- Seeking Participants

A study of Drug WWW in patients with advanced solid tumors

SEARCH RESULTS (OPTIONS), continued

“Map View”

Disclaimer: This interactive wireframe was designed by TransCelerate BioPharma for use in demonstrations to regulatory authorities. [Read More >](#)

ROTF Home About Clinical Trials Advanced Search For Researchers Help

Home > Search Results

Colorectal Cancer Philadelphia, PA (19125)

We have found 22 matching trials [Help me refine my results](#)

Condition: Colorectal Cancer x Distance: 25 miles x Location: Philadelphia, PA (19125) x Status: Seeking Participants x

Grid View Map View

FILTER BY Showing: 14 of 14 trials

Status

Trials:

☐ Seeking Participants

☐ Completed with Results

☐ All

Advanced

Distance

19125 25

Condition

Trial Type

Trial Phase

Intervention

Time Commitment

Placebo Possible

Age & Sex

Accepts Healthy Volunteers

Funder Type

Trial Results

Hidden Trials

A study of Drug ABC in patients...

name

A study of Drug ABC in patients with advanced Solid Tumors

description

Purpose: This is a multicenter, randomized, phase 3 study to evaluate Drug ABC in patients with KRAS mutant colorectal cancer. Read More >

Address: Location XYZ 126 S 11th St Philadelphia, PA 19125

Site Contact: 1800-555-5555

http://iz9r0.axshare.com/#g=1&p=trial_detail

“Compare Selected”

Disclaimer: This interactive wireframe was designed by TransCelerate BioPharma for use in demonstrations to regulatory authorities. [Read More >](#)

ROTF Home About Clinical Trials Advanced Search For Researchers Help

[Back to Search Results](#)

COMPARE SELECTED TRIALS

Name	A study of Drug ABC in patients with advanced Solid Tumors	A study of Drug TRX in patients with advanced Solid Tumors	A study of Treatment 123 in patients with advanced Solid Tumors
Purpose	This is a multicenter, randomized, phase 3 study to evaluate Drug ABC in patients with KRAS mutant colorectal cancer.	This is a multicenter, randomized, phase 3 study to evaluate Drug TRX in patients with KRAS mutant colorectal cancer.	This is a multicenter, randomized, phase 3 study to evaluate Treatment 123 in patients with KRAS mutant colorectal cancer.
Status	Seeking Participants	Seeking Participants	Seeking Participants
Distance	12 Miles	13 Miles	15 Miles
Nearest Location	Address: 126 S 11th St Philadelphia, PA 19125 See More Get Directions	Address: 857 Main Street Philadelphia, PA 19125 See More Get Directions	Address: 333 Lake Street Philadelphia, PA 19125 See More Get Directions
Condition	Colorectal Cancer, Colon Cancer	Colon Cancer	Colorectal Cancer
Type	Interventional	Interventional	Interventional
Phase	Phase 3	Phase 3	Phase 3
Intervention	Drug ABC	Drug TRX	Procedure 123
Time Commitment	Months 6 +/- Visits 15 +/-	Months 4 +/- Visits 18 +/-	Months 5 +/- Visits 14 +/-
Placebo	Participants will not receive placebo. Participants will receive either usual care (standard of care) in addition to the study intervention or usual care (standard of care) alone.	Participants will not receive placebo. Participants will receive either usual care (standard of care) in addition to the study intervention or usual care (standard of care) alone.	Participants will not receive placebo. Participants will receive either usual care (standard of care) in addition to the study intervention or usual care (standard of care) alone.
Age & Sex	Age: 18 + Sex: Female & Male	Age: 18 + Sex: Female & Male	Age: 18 + Sex: Female & Male
Accepts Healthy Volunteers	No	No	No
Funder Type	Industry	Academic	Government
Post-trial Treatment	Post trial treatment will be available	Post trial treatment will be available	Post trial treatment will be available
Site Services	Transportation to and from the trial site can be made available	Transportation to and from the trial site can be made available	Transportation to and from the trial site can be made available
Reimbursement	Coverage for Services: Yes Out of Pocket Expenses: Yes	Coverage for Services: Yes Out of Pocket Expenses: Yes	Coverage for Services: Yes Out of Pocket Expenses: Yes
Pay to Participate	No	No	No
My Notes	<input type="checkbox"/> Enter your notes here	<input type="checkbox"/> Ask my physician if I meet the inclusion criteria. Research information about intravenous therapies. Print this off and share with my kids to see what they think.	<input type="checkbox"/> Enter your notes here

View Trial	View Trial	View Trial
Bookmark	Bookmark	Bookmark

COMMUNITY

Social Feed Name 01.01.2017
Lorem ipsum dolor sit amet,
consectetur adipiscing elit. Aenean
euismod libero. Aenean.

NAVIGATION

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CONTACT

123 River St
Anywhere, PA
555.555.5555
FName.LName@email.com

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TRIAL DETAILS

Overview

After users have clicked on an individual trial, they are presented with the trial information page. The page organizes trial details in a structure and order most meaningful to a patient audience, minimizing the scrolling required to find information.

Disclaimer: This interactive wireframe was designed by TransCelerate BioPharma for use in demonstrations to regulatory authorities. [Read More >](#)

Home About Clinical Trials Advanced Search For Researchers Help

Home > Search Results > Trial Details

A study of Drug ABC in patients with advanced Solid Tumors

Status

Recruiting

Trial Type

Interventional

Phase

Phase 3

Sex

Female & Male

Age

18+

Participation Duration

+/- 6 mos.

Number of Visits

+/- 15

I'm Interested

Hide Trial

Search within this trial

OVERVIEW

PARTICIPATION

LOCATIONS

RESOURCES

TRIAL RESULTS

TRIAL PURPOSE

This is a multicenter, randomized, phase 3 study to evaluate Drug ABC in patients with KRAS mutant colorectal cancer. [Read More >](#)

Immunotherapy	No
Mechanism of Action	ABC 1 Inhibition
Molecular Composition of Tumor	KRAS Mutant

How do I know if this trial is right for me?

Outcome Measures

Basic Trial Details

Sponsor Information & Resources

Nearest Location: [Get Directions](#)

126 S 11th St

View larger map

Enter your personal notes here

People also viewed:

A study of Drug 1RX in patients with advanced Solid Tumors

View

A study of Drug 231 in patients with advanced Solid Tumors

View

A study of Drug WWW in patients with advanced Solid Tumors

View

View All

11. Outcome Measures: expandable sub-section listing the clinical outcomes identified for the trial.

12. Basic Trial Details: basic statistics and time stamps for the registry entry and for the overall trial.

- 1. Trial At-a-Glance:** the trial title and a set of standard iconography describing basic trial attributes is visible at the top of every trial information page.
- 2. "I'm Interested" button:** reveals a pop-up window indicating the preferred contact method for the nearest site location conducting the trial.
- 3. Search box:** allows users to search for key words found on the trial information page across all tabs and sections.
- 4. Bookmark, alerts, download, print and sharing features** operate in a similar manner to the search results page, but for individual trial information.
- 5. Notes:** allows users to type personal notes and, at their discretion, save the notes on the trial for future reference. Patient feedback revealed a desire to track questions or discussion points for conversations with a physician or family member.
- 6. Nearest Location on Map:** visual representation of the nearest site location for the clinical trial along with a link to retrieve directions.
- 7. People Also Viewed:** alternate method of trial search enabling users to view trials to which other users viewing this same trial have also navigated.
- 8. Sponsor Information & Resources:** transparent trial sponsor details, including trial sponsor category and contact information.
- 9. Trial Purpose:** summary of trial followed by an option to click "Read More" to reveal the full description.
- 10. How Do I Know if This Trial is Right for Me:** expandable sub-section clarifying the presence or type of placebo arm(s) on a trial and inclusion/exclusion (eligibility) criteria organized into several categories for easier comprehension.

The Participation Tab

Provides details which illustrate what it might be like to participate in the trial.

TRIAL DETAILS

Participation and Location

Users may navigate to additional tabs for more information about the trial.

- Potential Participation:** icons emphasize attributes relevant to participation and a brief series of short fields provides practical details for prospective trial participants.
- Visit by Visit:** displays an interactive timeline showing both the full scope of participation as well as individual visit details. Users may navigate to the details of each visit in the trial by clicking on each visit icon.
- Using information obtained with permission from each site location, a pop-up via the **"Contact"** button will display the preferred method of contact for each site.

The Location Tab

Provides both visual and list-based representations of the various site locations involved in a particular trial, regardless of individual site status.

The Resources Tab

Created to address patients' requests for additional connections to resources and communities relevant to their condition or diagnosis.

TRIAL DETAILS

Resources and Trial Results

Users may navigate to additional tabs for more information about the trial.

Disclaimer: This interactive wireframe was designed by TransCelerate BioPharma for use in demonstrations to regulatory authorities. [Read More >](#)

ROTF Home About Clinical Trials Advanced Search For Researchers Help

Home > Search Results > Trial Details

A study of Drug ABC in patients with advanced Solid Tumors

Status Recruiting

Trial Type Interventional

Phase Phase 3

Sex Female & Male

Age 18+

Participation Duration +/- 6 mos.

Number of Visits +/- 15

I'm Interested

Hide Trial

Search within this trial

OVERVIEW

PARTICIPATION

LOCATIONS

RESOURCES

TRIAL RESULTS

NOTES

NAME	TYPE	LINK
Group XYZ	Advocacy Group	www.GroupXYZ.com
Group ABC	Advocacy Group	www.GroupABC.com
Group 123	Advocacy Group	www.Group123.com
WebSource ABC	Informational	www.WebSourceABC.org
LMNOP Group	Patient Support	www.LMNOP-Group.com

Enter your personal notes here

A study of Drug 1RX in patients with advanced Solid Tumors [View](#)

A study of Drug 231 in patients with advanced Solid Tumors [View](#)

A study of Drug WWW in patients with advanced Solid Tumors [View](#)

[View All](#)

The Trial Results Tab

Created to house trial results fields currently specified by most major clinical trial registries along with links to additional documentation (such as lay summary results) where available. Users may also elect to be notified when trial results become available.

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Age 18+

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Number of Visits +/- 15

I'm Interested

Hide Trial

Search within this trial

OVERVIEW

PARTICIPATION

LOCATIONS

RESOURCES

TRIAL RESULTS

NOTES

There are no results for this trial at this time.

The sponsor of this clinical trial has chosen to provide lay summary results to all participants upon completion of the trial. General trial results will also be posted on this page after trial completion.

Would you like to be notified when results become available?

[NOTIFY ME](#)

Enter your personal notes here

A study of Drug 231 in patients with advanced Solid Tumors [View](#)

A study of Drug WWW in patients with advanced Solid Tumors [View](#)

[View All](#)

USER ACCOUNT

A user account enables additional features which help to personalize the experience and make the registry platform “go to work” for the user, such as the ability to:

- Save display or search preferences on the platform (preventing duplicate entry of criteria during successive trial searches or visits)
- Record and save personal notes about specific trials
- Bookmark individual trials or search types (sets of criteria) for future reference or use
- Set up automated alerts for trials matching previously entered criteria

Creating a user account should be optional and should not make mandatory the provision of any information beyond an email and a password.

Disclaimer: This interactive wireframe was designed by TransCelerate BioPharma for use in demonstrations to regulatory authorities. [Read More >](#)

ROTF Home About Clinical Trials Advanced Search For Researchers Help

Account Settings (UserJohnDoe) Search within settings

About Me

- General
- Search Criteria
- Medical Condition

General Info

Name (Optional)

Email JohnDoe@email.com

Phone (Optional)

Password (Change)

Language English

Time Zone Eastern Standard Time (EST)

Date / Time DD/MM/YYYY

Measurement Imperial (Mi / ft / lb)

Bookmarks & Alerts

- Bookmarks
- Alerts

Accessibility

Voice Over ☐ Yes ☒ No

Zoom 50% 100% 150%

Text Size S M L

High Contrast ☐ Yes ☒ No

Auto Speak Text ☐ Yes ☒ No

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ROTF Home About Clinical Trials Advanced Search For Researchers Help

Account Settings (UserJohnDoe) Search within settings

About Me

- General
- Search Criteria
- Medical Condition

Alerts

SEARCH NAME	DESCRIPTION	TEXT	EMAIL	FREQUENCY	ACTIONS
My Search 1	Showing 14 results - All trials have been looked at - waiting for new	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	New Results	
08/01/2017	Using multi-location (Phila & FL)	<input type="checkbox"/>	<input type="checkbox"/>	Frequency	
FL V Home	Search radius near vacation home in Florida	<input type="checkbox"/>	<input checked="" type="checkbox"/>	New Results	

Bookmarks & Alerts

- Bookmarks
- Alerts

TRIAL NAME	TEXT	EMAIL	FREQUENCY	ACTIONS
A study of Drug ABC in patients with advanced solid tumors	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Results Posted	



LEARN MORE

Read the full TransCelerate proposal for Clinical Trial Registry of the Future:

[“Improving the Value of Public Clinical Trial Registries to Patients: A Perspective and Call to Action”](#)



SPEAK OUT

Discuss the Clinical Trial Registry of the Future on social media using the hashtags #ClinicalTrial #RegistryOfTheFuture



SHARE THIS EBOOK

Use this eBook in conferences, summits or in discussion with peers as a point of reference for continued dialogue on facilitating patient-focused improvements to public clinical trial registries.

The Clinical Trial Registry of the Future wireframe proof of concept illustrated in this eBook was designed by TransCelerate BioPharma for use in demonstrations to government authorities. The wireframe provides examples of how government-sponsored clinical trial registries could be organized and operated more effectively to enable patients to obtain much greater value from the registries. The wireframe is offered “as is,” and nothing in the wireframe is meant to provide a legal opinion or imply compliance with relevant laws and regulations.