Update on ClinicalTrials.gov

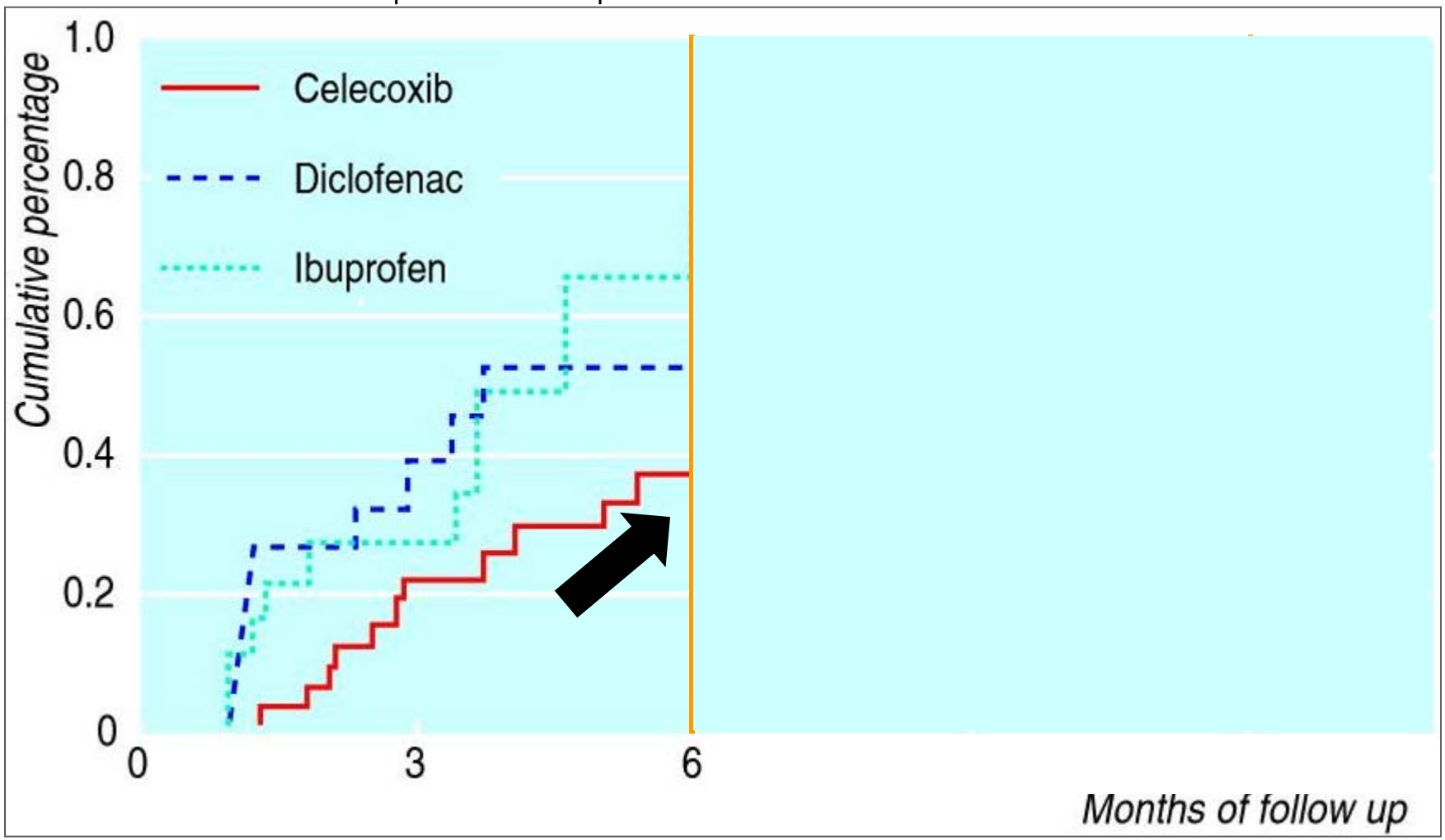
Deborah A. Zarin, M.D., Director
ClinicalTrials.gov
April 2017

Traditional System

- Design and conduct of clinical trials was left to individual investigators
  - No specific training required
  - Not much oversight of analytic methods
    - E.g., absence of scientific review of protocols at institutional level
- Individual investigators decided whether, when and how to disseminate results of clinical trials
  - Institutions assumed that fundamental academic incentives would ensure that this would happen;
  - But widespread appreciation that not all results would be reported

ClinicalTrials.gov

Kaplan-Meier estimates for ulcer complications according to traditional definition. Results are truncated after 12 months, no ulcer complications occurred after this period. Adapted from Lu 2001.



Jüni P, Rutjes AW, Dieppe PA. *BMJ*. 2002 Jun 1;324(7349):1287-8.

ClinicalTrials.gov – Milestones

- 1997 – FDA Modernization Act (FDAMA)
- 2000 - ClinicalTrials.gov launched
- 2005 - International Committee of Medical Journal Editors (ICMJE) trial registration policy
- 2007 - FDAAA 801* (Title VIII of Public Law 110-85)
  - Expanded clinical trial registration requirement and imposed new results submission requirements
  - Added enforcement provisions including up to $10,000/day in civil monetary penalties and withholding remaining or future grant funds
- 2016 – FDAAA 801 Final Rule (42 CFR Part 11) & NIH Clinical Trials Disclosure Policy

*FDAAA 801 = Section 801 of the Food and Drug Administration Amendments Act of 2007

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Evidence of Problems

- One practical problem:
  - Potential participants had trouble finding trials.
- Three scientific problems:
  - Not all trials are published
  - Not all outcome measures (or adverse events) are published
  - Changes to protocols are not always acknowledged

ClinicalTrials.gov

BMJ

BMJ 2011;344:d7292 doi: 10.1136/bmj.d7292 (Published 3 January 2012)

RESEARCH

Publication of NIH funded trials registered in ClinicalTrials.gov: cross sectional analysis


OPEN ACCESS

Joseph S Ross *assistant professor of medicine*[1 2], Tony Tse *program analyst at ClinicalTrials.gov*[3], Deborah A Zarin *director of ClinicalTrials.gov*[3], Hui Xu *postgraduate house staff trainee*[4], Lei Zhou *postgraduate house staff trainee*[4], Harlan M Krumholz *Harold H Hines Jr professor of medicine and professor of investigative medicine and of public health*[2 5 6]

[1]Section of General Internal Medicine, Department of Medicine, Yale University School of Medicine, New Haven, CT, USA; [2]Center for Outcomes Research and Evaluation, Yale-New Haven Hospital, New Haven, CT; [3]Lister Hill National Center for Biomedical Communications, National Library of Medicine, National Institutes of Health, Bethesda, MD, USA; [4]Fuwai Hospital and Cardiovascular Institute, Chinese Academy of Medical Sciences and Peking Union Medical College, Beijing, China; [5]Robert Wood Johnson Clinical Scholars Program and Section of Cardiovascular Medicine, Department of Medicine, Yale University School of Medicine, New Haven, CT; [6]Section of Health Policy and Administration, Yale University School of Epidemiology and Public Health, New Haven, CT

Reasons to Register Clinical Trials and Report Results

- Human Subject Protections
  - Allows potential participants to find studies
  - Assists ethical review boards and others to determine appropriateness of studies being reviewed (e.g., harms, benefits, redundancy)
  - Promote fulfillment of ethical responsibility to human volunteers – research contributes to medical knowledge
- Research Integrity
  - Facilitates tracking of protocol changes
  - Increases transparency of research enterprise
- Evidence Based Medicine
  - Facilitates tracking of studies and outcome measures
  - Allows for more complete identification of relevant studies
- Allocation of Resources
  - Promotes more efficient allocation of resources

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Key Clinical Trial Reporting Requirements

Reporting Requirement	ICMJE Policy (Effective in 2005)	FDAAA Final Rule (Issued in 2016)	Final NIH Policy (Issued in 2016)
Scope	Registration	Registration & Results Reporting	Registration & Results Reporting
Phase	All	Not Phase 1	All
Intervention Type	All	Drugs, Biologics, & Devices regulated by the FDA	All (e.g., including behavioral interventions)
Funding Source	Any	Any	NIH
Enforcement	Refusal to publish	Criminal proceedings and civil penalties (up to $10,000/day); Loss of HHS funding	Loss of NIH funding

Content of a Study Record
(Minimum Information Requirements)

- **Registration section**
  - Submitted at trial initiation
  - Summarizes information from trial protocol: e.g.,
    - Condition
    - Interventions
    - Study Design
  - Includes recruitment information (e.g., eligibility, locations)

- **Results section**
  - Submitted after trial completion
  - Summarizes trial results
    - Participant flow
    - Baseline characteristics
    - Outcome measures (including statistical analyses)
    - Adverse events

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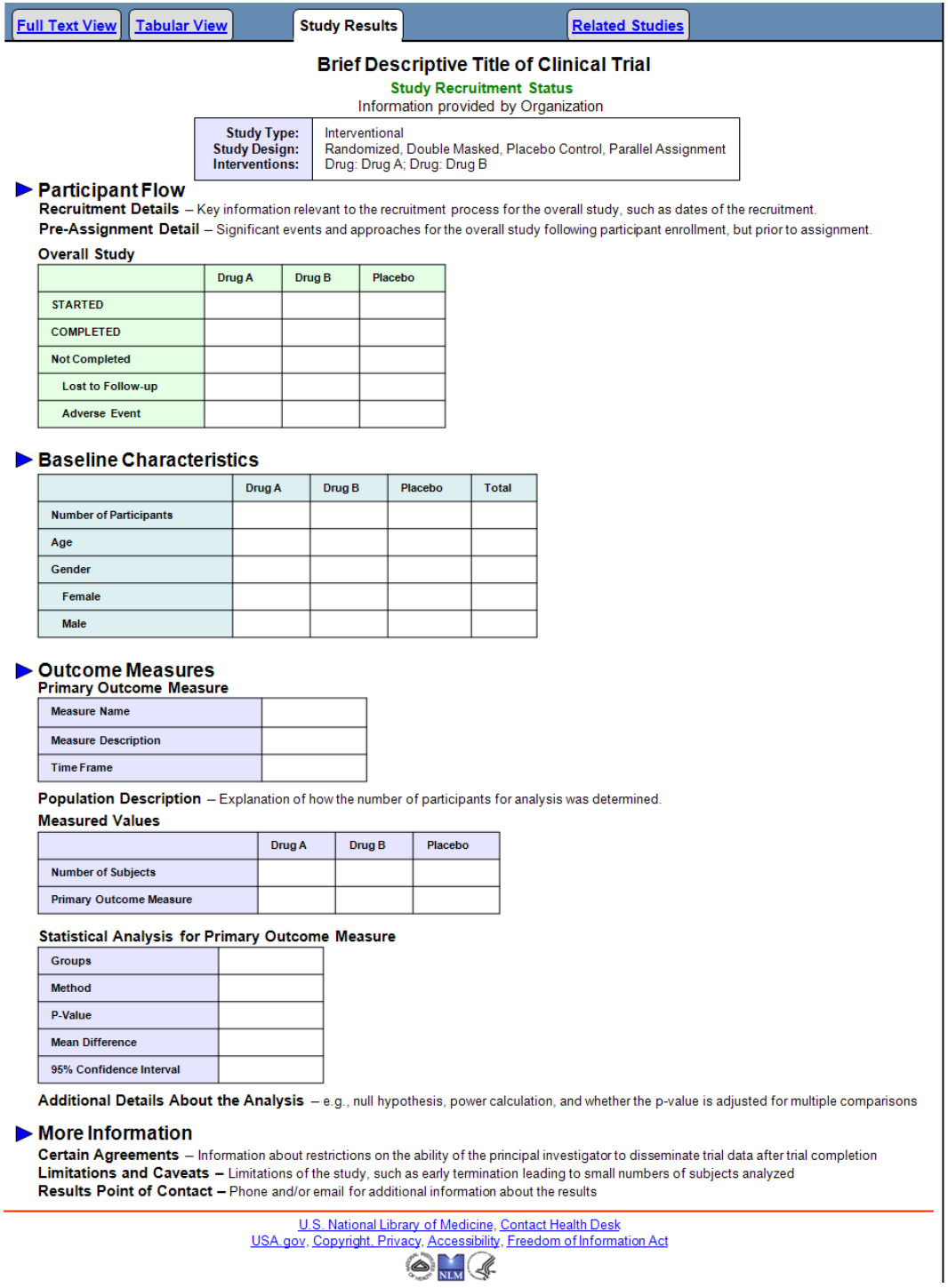

Full Text View | Tabular View | Study Results | Related Studies

Brief Descriptive Title of Clinical Trial

Study Recruitment Status

Information provided by Organization

Study Type:	Interventional
Study Design:	Randomized, Double Masked, Placebo Control, Parallel Assignment
Interventions:	Drug: Drug A; Drug: Drug B

Participant Flow

Recruitment Details – Key information relevant to the recruitment process for the overall study, such as dates of the recruitment.

Pre-Assignment Detail – Significant events and approaches for the overall study following participant enrollment, but prior to assignment.

Overall Study

	Drug A	Drug B	Placebo
STARTED			
COMPLETED			
Not Completed			
Lost to Follow-up			
Adverse Event			

Baseline Characteristics

	Drug A	Drug B	Placebo	Total
Number of Participants				
Age				
Gender				
Female				
Male				

Outcome Measures

Primary Outcome Measure

Measure Name	
Measure Description	
Time Frame	

Population Description – Explanation of how the number of participants for analysis was determined.

Measured Values

	Drug A	Drug B	Placebo
Number of Subjects			
Primary Outcome Measure			

Statistical Analysis for Primary Outcome Measure

Groups	
Method	
P-Value	
Mean Difference	
95% Confidence Interval	

Additional Details About the Analysis – e.g., null hypothesis, power calculation, and whether the p-value is adjusted for multiple comparisons

More Information

Certain Agreements – Information about restrictions on the ability of the principal investigator to disseminate trial data after trial completion

Limitations and Caveats – Limitations of the study, such as early termination leading to small numbers of subjects analyzed

Results Point of Contact – Phone and/or email for additional information about the results

U.S. National Library of Medicine, Contact Health Desk
USA.gov, Copyright, Privacy, Accessibility, Freedom of Information Act

4 Scientific Modules

- Participant Flow
- Baseline Characteristics
- Outcome Measures
- Adverse Events

Administrative Information
e.g., “Certain Agreements”

ClinicalTrials.gov Reporting Volume
(as of 19 Apr 2017)

- Registration
  - 242,000 study records
  - 600 submissions/week
  - 16,500 data providers (sponsors and investigators)
- Summary Results Reporting
  - 26,000 records with results posted
  - About 50% have associated publications
  - 140 submissions/week
  - 2,800 data providers
- Usage Stats
  - 199+ million page views/month
  - 1.1M+ unique visitors/month

ClinicalTrials.gov

Potential Consequences of Non-Compliance with FDAAA

- NIH (or other HHS agency) must verify submission of information before releasing any remaining funds for a grant or funds for a future grant and provide opportunity to remedy
- FDA may provide responsible parties with a Notice of Noncompliance and allow 30 days to remedy
  - Compliance with registration and results reporting requirements listed in FDA BIMO inspection SOPs
- FDA authorized to assess civil monetary penalties up to $10,000/day (amounts adjusted going forward)
- FDA may initiate civil or criminal proceedings
- Notices of non-compliance to be included in the public record
  - 21st Century Cures Act (P.L. 114-255) Section 2052 requires NIH and FDA to issue of Compliance Activities Reports to Congressional committees

The NEW ENGLAND JOURNAL of MEDICINE

SPECIAL REPORT

Trial Reporting in ClinicalTrials.gov — The Final Rule

Deborah A. Zarin, M.D., Tony Tse, Ph.D., Rebecca J. Williams, Pharm.D., M.P.H., and Sarah Carr, B.A.

Title VIII of the Food and Drug Administration (FDA) Amendments Act of 2007 (FDAAA) expanded the legal mandate for sponsors and others responsible for certain clinical trials of FDA-regulated drug, biologic, and device products to register their studies and report summary results information to ClinicalTrials.gov,[1] which is managed by the National Library of Medicine at the National Institutes of Health (NIH). The statute expanded registration requirements and provided a legally defined timeline with specific requirements for the systematic reporting of summary trial results. Although statutory components took effect before 2010, the FDAAA directed the Department of Health and Human Services (HHS) to issue regulations regarding certain statutory provisions and to consider possible expansion of the requirements through rulemaking.

developed the final rule, which was made publicly available on September 16, 2016. Simultaneously, the NIH issued a complementary final policy, under which NIH-funded awardees and investigators will be expected to submit registration and results information for all NIH-funded clinical trials, whether or not the trials are covered by the FDAAA requirements.[6]

Here, we summarize and highlight key points about the final rule (see box).

BACKGROUND

The FDAAA established legal requirements for sponsors and designated principal investigators (i.e., responsible parties) to report specified clinical trial information for certain applicable clinical trials to ClinicalTrials.gov. In addition to registration, the statute established a system and man-

Source: *N Engl J Med*. 2016 Nov 17;375(20):1998-2004.

ClinicalTrials.gov Results Database versus Journal Publication

- ClinicalTrials.gov provides “minimum dataset”
  - Participant flow, baseline, all outcome measures, adverse events
  - Minimal narrative—no conclusions
- Journals provide background, data and discussion
  - Peer review focuses on interest and relevance of study, consistency of conclusions and data;
- ClinicalTrials.gov ensures
  - Complete reporting, whether or not publication occurs
  - Covers the gap between announcement of results and journal publication
  - Facilitates structured search
- About 50% of ClinicalTrials.gov entries have no associated publications

OPEN ACCESS Freely available online

PLOS | MEDICINE

Timing and Completeness of Trial Results Posted at ClinicalTrials.gov and Published in Journals

Carolina Riveros[1,2,3], Agnes Dechartres[1,2,3]*, Elodie Perrodeau[1,3], Romana Haneef[1,3], Isabelle Boutron[1,2,3,4], Philippe Ravaud[1,2,3,4,5]

1 INSERM U738, Paris, France, **2** Université Paris Descartes—Sorbonne Paris Cité, Paris, France, **3** Centre d'Épidémiologie Clinique, Hôpital Hôtel-Dieu, Assistance Publique-Hôpitaux de Paris, Paris, France, **4** French Cochrane Centre, Paris, France, **5** Mailman School of Public Health, Columbia University, New York, New York, United States of America

Findings: "Reporting was significantly more complete at ClinicalTrials.gov than in the published article for the flow of participants (64% versus 48% of trials, p,0.001), efficacy results (79% versus 69%, p = 0.02), adverse events (73% versus 45%, p,0.001), and serious adverse events (99% versus 63%, p,0.001)."

Conclusions: "Our results highlight the need to search ClinicalTrials.gov for both unpublished and published trials. Trial results, especially serious adverse events, are more completely reported at ClinicalTrials.gov than in the published article."

Source: *PLoS Med*. 2013 10(12): e1001566

Which of These Would You Not Need?

- Baseline Characteristics
  - One table, for each arm and overall
  - Age (continuous or categorical)
  - Gender
- Participant Flow
  - # Started and
    # completed each arm
- Outcome Measures
  - Summary data for each prespecified Primary and Secondary Outcome Measure (per arm)
- Adverse Events
  - Table of all Serious Adverse Events (per arm)
  - Table of "other" Adverse Events that occur in more than 5% of participants (per arm)

ClinicalTrials.gov

FLAME Trial: Linking Published Article & ClinicalTrials.gov Results Database Entry

"The protocol includes a list of 27 secondary outcome measures; we report data for 19 of these outcomes here and in Sections 4 and 5 in the Supplementary Appendix. The outcomes for which data are not reported herein can be found at ClinicalTrials.gov (https://clinicaltrials.gov/ct2/show/results/NCT01782326)."

ClinicalTrials.gov

Wedzicha JA et al. *N Engl J Med*. 2016 Jun 9;374(23):2222-34.

The NE
JOUR

HOME | ARTICLES & MULTIMEDIA

ORIGINAL ARTICLE

Indacaterol–Glycopyr
COPD

Jadwiga A. Wedzicha, M.D., Donald Ban
Roche, M.D., R. Timothy Ayers, M.Sc., C
Vogelmeier, M.D., for the FLAME Investig
N Engl J Med 2016; 374:2222-2234 | Jun

Abstract | Article | References

glycopyrronium would be superio
exacerbations.

The protocol includes a list of 27
outcomes here and in Sections 4
data are not reported herein can
/results/NCT01782326). Seconda
a severity, the first moderate o
exacerbation and the annual rate
exacerbations. We also assessed
from 0 to 12 hours (in a subgroup
George's Respiratory Questionna
with higher scores indicating wors
4 points, as compared with the score with placebo[24]), and the use of rescue medication.

ClinicalTrials.gov
A service of the U.S. National Institutes of Health

Example: "Heart attack" AND "Los Angeles"
Search for studies: Search
Advanced Search | Help | Studies by Topic | Glossary

Find Studies | About Clinical Studies | Submit Studies | Resources | About This Site

Home > Find Studies > Study Record Detail

Text Size

QVA vs. Salmeterol/Fluticasone, 52-week Exacerbation Study, FLAME (EFfect of Indacaterol Glycopyronium Vs Fluticasone Salmeterol on COPD Exacerbations)

This study has been completed.

Sponsor:
Novartis Pharmaceuticals

Information provided by (Responsible Party):
Novartis (Novartis Pharmaceuticals)

ClinicalTrials.gov Identifier:
NCT01782326

First received: January 30, 2013
Last updated: May 5, 2016
Last verified: May 2016
History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Results First Received: May 4, 2016

Measured Values

	QVA149	Long Acting B2 Agonist (LABA) and Inhaled Corticosteroid (ICS)
Number of Participants Analyzed [units: participants]	1528	1556
Rate of COPD Exacerbations [units: COPD Exacerbations/year] Least Squares Mean (95% Confidence Interval)	3.59 (3.28 to 3.94)	4.03 (3.68 to 4.41)

Statistical Analysis 1 for Rate of COPD Exacerbations

Groups [1]	All groups
Non-Inferiority/Equivalence Test [2]	Yes
Method [3]	Generalized linear model
Rate Ratio [4]	0.89
95% Confidence Interval	0.83 to 0.96

The NEW ENGLAND JOURNAL of MEDICINE

SPECIAL REPORT

Update on Trial Registration 11 Years after the ICMJE Policy Was Established

Deborah A. Zarin, M.D., Tony Tse, Ph.D., Rebecca J. Williams, Pharm.D., M.P.H., and Thiyagu Rajakannan, Ph.D.

Laws and policies to establish a global trial reporting system have greatly increased the transparency and accountability of the clinical research enterprise. The three components of the trial reporting system are trial registration, reporting of aggregate results, and sharing of individual participant data.[1] Trial registration is foundational to our understanding and interpretation of trial results, because it requires that information be provided about all relevant clinical trials (to put results in a broad context) and their prespecified protocol details (to ensure adherence to the scientific plan).

In this article, we describe the current trial registration landscape and summarize evidence of its effect on the clinical research enterprise to date. We then present the results of analyses that were performed with the use of ClinicalTrials.gov data to provide additional evidence regarding the degree to which current practices are fulfilling certain key goals initially envisioned for trial registration. Finally, we identify challenges and suggest potential responses for the next decade.

tion of clinical research findings into the medical evidence base. The second goal is to provide access to date-stamped protocol amendments that occur during the trial. Access to structured archival information allows the public to track the progress of individual studies and assess whether reported results are consistent with the prespecified protocol or statistical analysis plan.

EVOLUTION OF THE GLOBAL TRIAL REPORTING SYSTEM

After the announcement of the International Committee of Medical Journal Editors (ICMJE) trial registration policy[2] in September 2004, a series of related laws and policies were implemented in the United States[3] and internationally[4] that increased the scope and content of mandatory prospective trial registration. The World Health Organization International Clinical Trials Registry Platform established the Trial Registration Data Set standard,[5] which is the minimum set of data to be provided during trial registra-

ClinicalTrials.gov

ORIGINAL CONTRIBUTION

Characteristics of Clinical Trials Registered in ClinicalTrials.gov, 2007-2010

Robert M. Califf, MD
Deborah A. Zarin, MD
Judith M. Kramer, MD, MS
Rachel E. Sherman, MD, MPH
Laura H. Aberle, BSPH
Asba Tasneem, PhD

Context Recent reports highlight gaps between guidelines-based treatment recommendations and evidence from clinical trials that supports those recommendations. Strengthened reporting requirements for studies registered with ClinicalTrials.gov enable a comprehensive evaluation of the national trials portfolio.

Objective To examine fundamental characteristics of interventional clinical trials registered in the ClinicalTrials.gov database.

Methods A data set comprising 96 346 clinical studies from ClinicalTrials.gov was

"Conclusion Clinical trials registered in ClinicalTrials.gov are dominated by small trials and contain significant heterogeneity in methodological approaches, including reported use of randomization, blinding, and DMCs."

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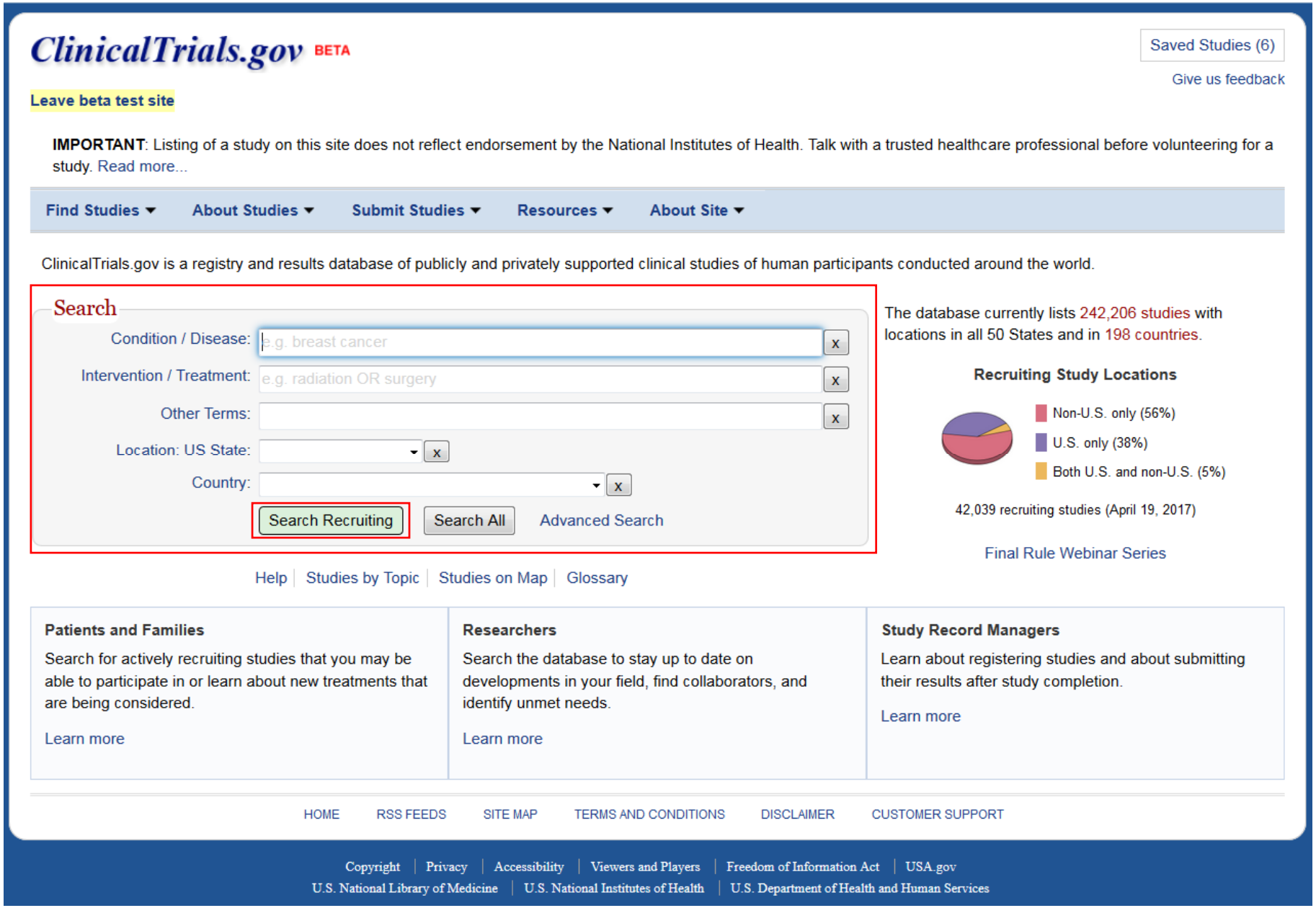
Journal Editors (ICMJE) announced a policy, which took effect in 2005, of requiring registration of clinical trials as a prerequisite for publication.[6,7] The Food and Drug Administration Amendment Act (FDAAA)[8] expanded the mandate of ClinicalTrials.gov to include most non-

randomization and blinding were less frequently reported in earlier-phase, oncology, and device trials.

Conclusion Clinical trials registered in ClinicalTrials.gov are dominated by small trials and contain significant heterogeneity in methodological approaches, including reported use of randomization, blinding, and DMCs.

JAMA. 2012;307(17):1838-1847 www.jama.com

Ongoing Work to Improve the Public Site


ClinicalTrials.gov BETA
Saved Studies (6)
Give us feedback
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IMPORTANT: Listing of a study on this site does not reflect endorsement by the National Institutes of Health. Talk with a trusted healthcare professional before volunteering for a study. Read more...
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About Site
ClinicalTrials.gov is a registry and results database of publicly and privately supported clinical studies of human participants conducted around the world.
Search
Condition / Disease:
e.g. breast cancer
Intervention / Treatment:
e.g. radiation OR surgery
Other Terms:
Location: US State:
Country:
Search Recruiting
Search All
Advanced Search
The database currently lists 242,206 studies with locations in all 50 States and in 198 countries.
Recruiting Study Locations
Non-U.S. only (56%)
U.S. only (38%)
Both U.S. and non-U.S. (5%)
42,039 recruiting studies (April 19, 2017)
Final Rule Webinar Series
Help
Studies by Topic
Studies on Map
Glossary
Patients and Families
Search for actively recruiting studies that you may be able to participate in or learn about new treatments that are being considered.
Learn more
Researchers
Search the database to stay up to date on developments in your field, find collaborators, and identify unmet needs.
Learn more
Study Record Managers
Learn about registering studies and about submitting their results after study completion.
Learn more
HOME
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SITE MAP
TERMS AND CONDITIONS
DISCLAIMER
CUSTOMER SUPPORT
Copyright
Privacy
Accessibility
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Saved Studies (6)
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ClinicalTrials.gov is a registry and results database of publicly and privately supported clinical studies of human participants conducted around the world.
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Condition / Disease:
breast cancer
Intervention / Treatment:
Other Terms:
Location: US State:
Country:
Breast Cancer
Breast Cancer Female
Breast Cancer Stage IV
Breast Cancer Stage
Breast Cancer Stage IIB
Breast Cancer Model
Breast Cancer Stage II
Breast Cancer and Pregnancy
Breast Cancer Invasive
Breast Cancer Stage I
All
Advanced Search
Glossary
The database currently lists 242,206 studies with locations in all 50 States and in 198 countries.
Recruiting Study Locations
Non-U.S. only (56%)
U.S. only (38%)
Both U.S. and non-U.S. (5%)
42,039 recruiting studies (April 19, 2017)
Final Rule Webinar Series
Patients and Families
Search for actively recruiting studies that you may be able to participate in or learn about new treatments that are being considered.
Learn more
Researchers
Search the database to stay up to date on developments in your field, find collaborators, and identify unmet needs.
Learn more
Study Record Managers
Learn about registering studies and about submitting their results after study completion.
Learn more
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DISCLAIMER
CUSTOMER SUPPORT
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Accessibility
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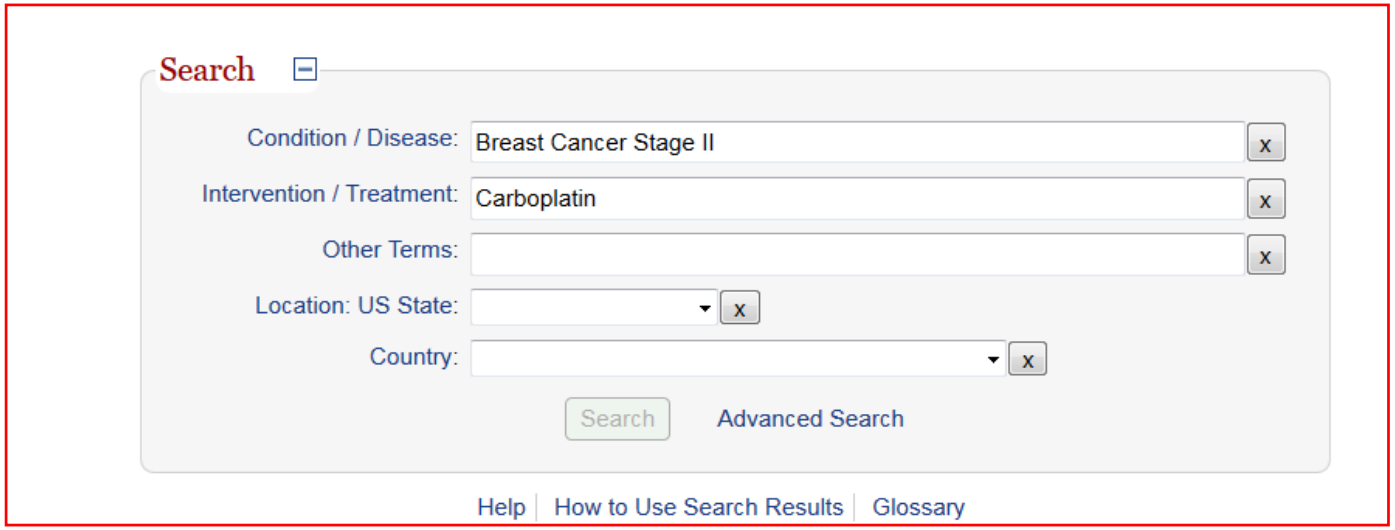
Freedom of Information Act
USA.gov
U.S. National Library of Medicine
U.S. National Institutes of Health
U.S. Department of Health and Human Services



126 Studies found

List | By Topic | On Map | Search Details

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Showing: 1-10 of **126** studies 10 studies per page

Show/Hide Columns

Filters

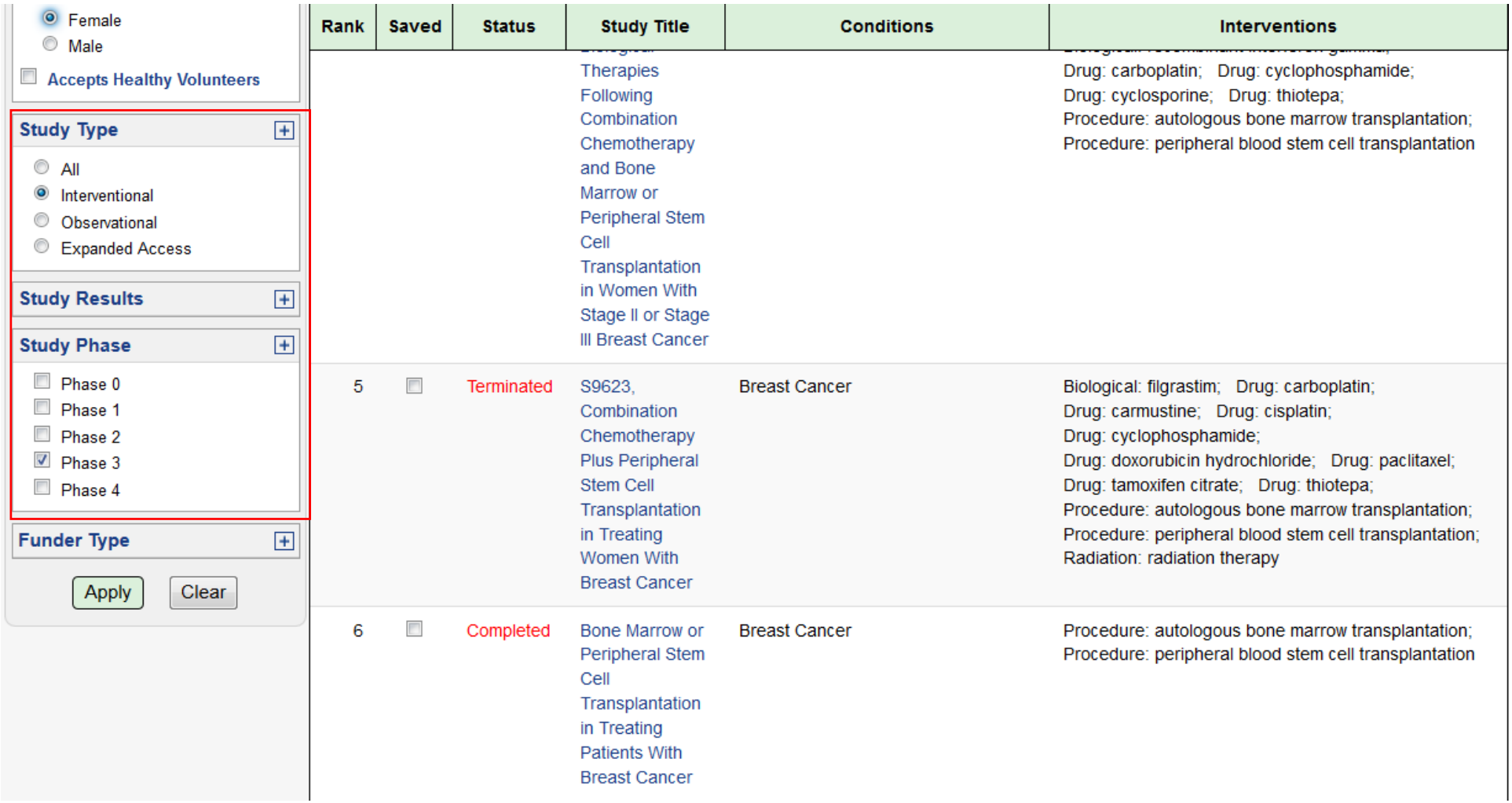
Apply Clear

Status

Studies:

- Not yet recruiting
- Recruiting
- Enrolling by invitation
- Active, not recruiting
- Suspended
- Terminated

Rank	Saved	Status	Study Title	Conditions	Interventions
1		Recruiting	Predictors of Response to Neoadjuvant Docetaxel-Carboplatin Chemotherapy for Patients With Stage II and III Triple Negative Breast Cancer	Breast Cancer; Breast Cancer Stage II-III	Drug: Docetaxel- Carboplatin


Female
Male
Accepts Healthy Volunteers
Study Type
All
Interventional
Observational
Expanded Access
Study Results
Study Phase
Phase 0
Phase 1
Phase 2
Phase 3
Phase 4
Funder Type
Apply
Clear
Rank
Saved
Status
Study Title
Conditions
Interventions
Therapies Following Combination Chemotherapy and Bone Marrow or Peripheral Stem Cell Transplantation in Women With Stage II or Stage III Breast Cancer
Drug: carboplatin; Drug: cyclophosphamide;
Drug: cyclosporine; Drug: thiotepa;
Procedure: autologous bone marrow transplantation;
Procedure: peripheral blood stem cell transplantation
5
Terminated
S9623, Combination Chemotherapy Plus Peripheral Stem Cell Transplantation in Treating Women With Breast Cancer
Breast Cancer
Biological: filgrastim; Drug: carboplatin;
Drug: carmustine; Drug: cisplatin;
Drug: cyclophosphamide;
Drug: doxorubicin hydrochloride; Drug: paclitaxel;
Drug: tamoxifen citrate; Drug: thiotepa;
Procedure: autologous bone marrow transplantation;
Procedure: peripheral blood stem cell transplantation;
Radiation: radiation therapy
6
Completed
Bone Marrow or Peripheral Stem Cell Transplantation in Treating Patients With Breast Cancer
Breast Cancer
Procedure: autologous bone marrow transplantation;
Procedure: peripheral blood stem cell transplantation

Sample Uses of ClinicalTrials.gov Data

Basic Uses of ClinicalTrials.gov

- Identify trials of potential interest for an individual
  - Including to specific user communities
- Track progress of a specific trial, including availability of summary results
- Identify all trials that are completed or ongoing for a specific set of conditions/interventions
  - Complement to literature review
  - Useful in planning stages of a new protocol
- Identify investigators and/or research centers of relevance to a specific set of conditions/ interventions

ClinicalTrials.gov

For those concerned with human subjects protections…

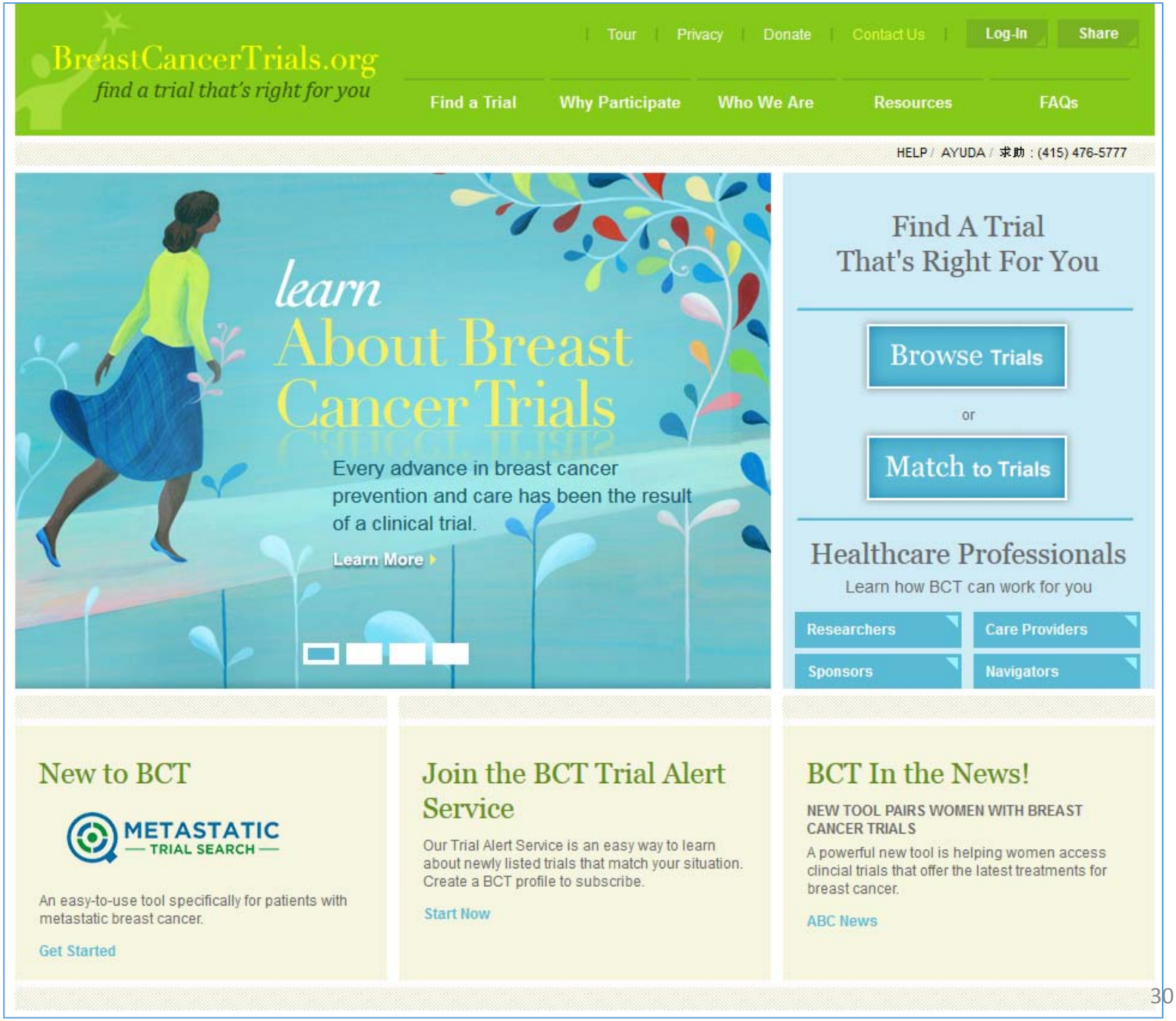
- Complete list of ongoing and completed trials of relevance
- Assurance that information about the trial of interest
  - is in the public domain
  - for some trials, results will become public

ClinicalTrials.gov

For those with medical conditions…

- Finding a trial in which to participate
- Finding an expanded access drug
- Finding a center of research for a given condition/intervention

ClinicalTrials.gov


BreastCancerTrials.org
find a trial that's right for you
Tour | Privacy | Donate | Contact Us | Log-In | Share
Find a Trial | Why Participate | Who We Are | Resources | FAQs
HELP / AYUDA / 求助 : (415) 476-5777
learn
About Breast Cancer Trials
Every advance in breast cancer prevention and care has been the result of a clinical trial.
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Researchers
Care Providers
Sponsors
Navigators
New to BCT
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NEW TOOL PAIRS WOMEN WITH BREAST CANCER TRIALS
A powerful new tool is helping women access clincial trials that offer the latest treatments for breast cancer.
ABC News

For those concerned with research integrity and methods…

- Relatively complete list of trials
- Description of protocol
- Tracking of changes to protocols
- Identifying all outcome measures
- Providing results, regardless of journal publication status
- Provides method of overseeing types of trial methods being used, e.g.
  - OM specification; non-inferiority designs; single-arm studies;

ClinicalTrials.gov

For those seeking study results…

- Linkages to PubMed
- Summary Results in database
  - About 60% not available in PubMed
- Results for all prespecified outcome measures
- Standardized format facilitating comparisons

ClinicalTrials.gov

For those seeking to use aggregate data…

- Search engine allows one to identify all trials that meet certain criteria
  - Search results are listed by relevance
- Must understand nuances of database
- May be best to call for help
- Alternative site to find ClinicalTrials.gov data; CTTI:
  - http://www.ctti-clinicaltrials.org/what-we-do/analysis-dissemination/state-clinical-trials

Questions?

register@clinicaltrials.gov