Regulatory Restrictions on "Promotion" of Investigational Products

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Global Regulatory Affairs | Janssen Research & Development, LLC

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Artwork from, Reflections Art in Health
a user-led charity that promotes positive
mental health through the creative arts.

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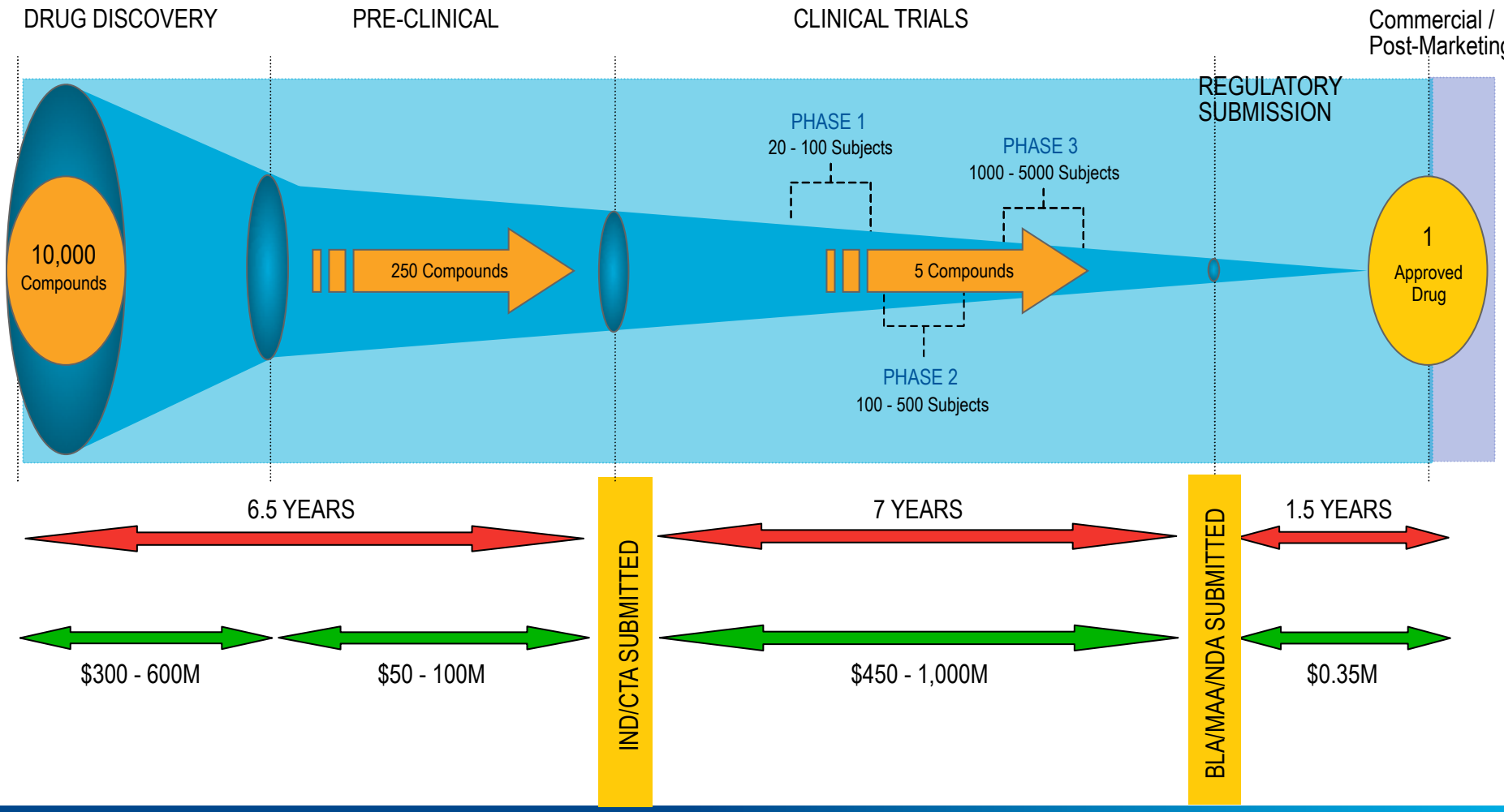
Agenda

- Context & Current Regulations
- Translation into Clinical Trial Recruitment Ads (CTRA)
- The BIG Rules
- 21st Century Patients– Providing Information about Clinical Trials
- Questions for Consideration

Drug Development Cycle



The Fundamentals…

Communications about investigational drugs should be clearly distinguished from promotional materials

21 CFR 312.7 Promotion of Investigational Drugs

- Prohibited from representing that an investigational drug is safe or effective for the use for which it is under investigation
- Does allow for the full exchange of scientific information to scientific or lay media about investigational drugs
- Allows corporate communications that do not represent that a drug is safe or effective for an unapproved new use or otherwise commercialize an unapproved drug

Typical requirements of CTRAs

- IRB Approval
- No claims, explicitly or implicitly, that the investigational product is safe or effective for the use for which it is under investigation or is comparable, equivalent, or superior to another intervention.
- Ordinarily cannot mention by name the actual investigational medication

Items Generally Included in CTRA

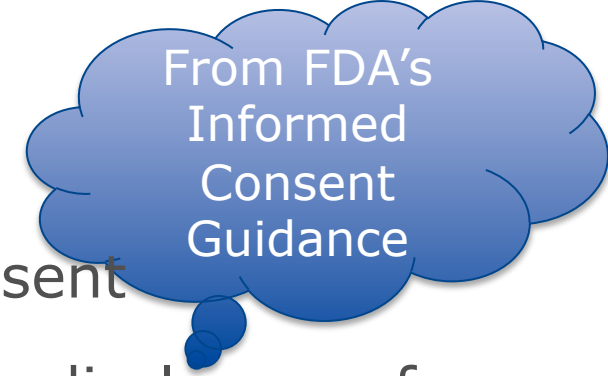
- Name and address of clinical investigator or research facility
- The condition under study and/or purpose of the research
- Summary of eligibility criteria
- If any, a brief list of participation benefits (eg, exams and medications at no cost)
- Time or other commitment required
- Location of the research and contact numbers/ persons

Essential to Avoid

Creating an expectation of benefit—appealing to emotional vulnerability

- "I wish my illness would go away"
- "[DISEASE] can have a devastating effect on your social life, causing feelings of frustration, sadness, and embarrassment"
- "If you suffer from [DISEASE], have we got a study for you!"

Informed Consent & Recruitment

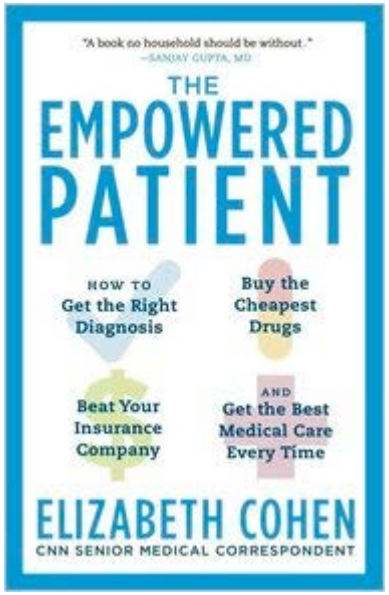


- An ad is the beginning of informed consent
- Informed consent requires an adequate disclosure of potential benefits and potential risks, and is otherwise free of coercion
- Thus a recruitment ad conveying an expectation of benefit will have to convey an expectation of risks. For example:
  - Risk of serious infections, worsening of heart failure, major bleeds, etc.
  - Risk of treatment failure
  - Fact that additional risks are unknown
  - Fact that patients may not be randomized to investigational medication and may receive current standard of care or placebo
  - And so on…

Key Principles

- Ad cannot be coercive
  - Ad should be informative, but not persuasive
- Should not convey expectation of safety or efficacy benefit
- Ads should avoid
  - Guilt
    - Don’t you think it’s time?
    - Are you embarrassed?
    - Haven’t you suffered long enough?
    - Isn’t it time you made a difference?
  - Any statements that suggest that studies are a good way for patients to get treatment they otherwise couldn’t afford
  - Emphasis on payment, other than stating that patients will be compensated for time and travel, study related exams and medications provided at no cost

A Time of Transition



Transformation of Patient Involvement in Healthcare: Enablers

The Empowered Patient and Patient Organizations

Technology Advancements Driving Information Access

Consumer Offerings
Health information websites & apps, provider ratings, comparison tools

Data
Sensor & monitoring devices, algorithms, visualization, risk identifiers

Social Connectivity
Social media & data sharing, peer reviews, peer pacts, wellness tracking, games

Communication Platforms
Real time physician access, remote visits, retail clinics

Information Systems
Cloud based records, secure collaboration networks, patient-friendly records

Demands on Access and Reimbursement

Drug Approval
Burden of proof requirements, benefit-risk, PROs

Outcomes Metrics
Value-based pricing, standard performance measures, alternative care delivery

Cost Management
More coverage options, chronic care tools, HTAs, co-pay trade-offs, wellness programs

FOX TRIAL FINDER

THE MICHAEL J. FOX FOUNDATION FOR PARKINSON'S RESEARCH

SHARE: English

Log In / Register

ABOUT FOX TRIAL FINDER | UNDERSTANDING CLINICAL TRIALS | BROWSE TRIALS | FOR RESEARCHERS

FIND A TRIAL

- I have Parkinson's
  or am registering for someone who does
- I do not have Parkinson's
  but would like to volunteer for a trial

I am located in

Please choose a country

Postal Code

GET STARTED

ABOUT FOX TRIAL FINDER

Fox Trial Finder was created by the Michael J. Fox Foundation to help increase the flow of willing participants — both people with Parkinson's and control participants who do not have Parkinson's — into the clinical trials that need them, accelerating the Parkinson's drug development process.

Clinical trials are a final and crucial step on the path to developing better treatments for Parkinson's patients today. Around the world, between 40% and 70% of trials face delays because of a lack of volunteers.

Fox Trial Finder will not only list ongoing PD clinical trials and research studies, but will match registrants to the trials that need them and are best-suited to their specific traits. Fox Trial Finder also has a secure and anonymous messaging system , making it much easier to find and act on suitable opportunities to get involved.

FROM MICHAEL J. FOX

"The answer is truly in all of us, working together. International collaboration is essential for speeding a cure for the 5 million Parkinson's patients worldwide."

— Michael J. Fox

TRIAL TEAMS

Do you need volunteers for your clinical trial? Find them with Fox

ChallengePost Find Challenges Post Challenges Log in Sign up

Patient Engagement APP CHALLENGE

Submissions open soon (view all dates) $40,000 in prizes

Transform the clinical trial experience for patients — submit apps that educate, engage, and empower participants enrolled in clinical studies.

REGISTER

Submissions open on November 4th, 2013.

Register now to ensure you receive all updates about the challenge!

About the Challenge

Submissions open soon (view all dates)

We all want the most advanced medical treatments, but few truly understand what goes into making medical advancements possible. Clinical research plays a vital role in the process of bringing new treatments to patients and advancing clinical care. However, despite its importance, there are multiple challenges associated with clinical research, with participant engagement and retention being one of them.

To combat this problem, the Partnerships in Clinical Trials Team/IIRUSA is partnering with industry leaders including Eli Lilly & Co, and UBC to promote patient-centered clinical research through the Patient Engagement App Challenge.

Created By

Lilly

UBC AN EXPRESS SCRIPTS COMPANY

PARTNERSHIPS IN CLINICAL TRIALS

The 23rd Annual Partnerships in Clinical Trials Conference is the premiere clinical trials meeting in the world – attracting the highest-

ClinicalTrials.gov

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

ClinicalTrials.gov is a registry and results database of publicly and privately supported clinical studies of human participants conducted around the world. Learn more about clinical studies and about this site, including relevant history, policies, and laws.

Now Available for Public Comment: Notice of Proposed Rulemaking (NPRM) for FDAAA 801 and NIH Draft Reporting Policy for NIH-Funded Trials

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

ClinicalTrials.gov currently lists 182,394 studies with locations in all 50 states and in 187 countries.

Text Size

Search for Studies

Example: "Heart attack" AND "Los Angeles"

Search

Advanced Search | See Studies by Topic

See Studies on a Map

Search Help

- How to search
- How to find results of studies
- How to read a study record

For Patients & Families

- How to find studies
- See studies by topic
- Learn about clinical studies
- Learn more...

For Researchers

- How to submit studies
- Download content for analysis
- About the results database
- Learn more...

For Study Record Managers

- Why register?
- How to register study records
- FDAAA 801 Requirements
- Learn more...

Locations of Recruiting Studies

- Non-U.S. Only (52%)
- U.S. Only (42%)
- Both U.S. and Non-U.S. (6%)

Total N = 34,312 studies
Data as of January 15, 2015

- See more trends, charts, and maps

Learn More

- ClinicalTrials.gov Online Training
- Glossary of common site terms

For the Press

Using our RSS Feeds

DRUG TRIALS SUMMARY:

What is the drug for?

DALVANCE is used to treat serious bacterial skin infections known as acute bacterial skin and skin structure infections (ABSSSI). DALVANCE should be used only to treat infections that are proven or strongly suspected to be caused by susceptible strains of Gram-positive microorganisms.

How do I use this drug?

DALVANCE is recommended as a two-dose regimen, each dose separated by one week. The drug is administered by a health care professional as an intravenous infusion (IV) over the course of about 30 minutes.

What are the benefits of this drug?

The results of the clinical studies showed a majority of patients treated with DALVANCE stopped the spread of their skin infection and eliminated fever within 2-3 days.

Were there any differences in how well the drug worked in clinical trials among sex, race and age?

Subgroup analyses were conducted for sex, race and age.

- **Sex:** DALVANCE was shown to be similarly effective in men and women.
- **Race:** Subgroup analyses were conducted for non-whites and whites, but the number of patients in the non-white subgroup was limited. If there were differences in response to DALVANCE versus the comparator, it may not have been able to be detected.
- **Age:** DALVANCE is similarly effective in patients above and below age 65.

FDA's Drugs Trials Snapshot Pilot

What are the possible side effects?

The most common adverse reactions in patients treated with DALVANCE were nausea (5.5%), headache (4.7%), and diarrhea (4.4%). Other side effects included vomiting, rash, and itching. Serious allergic reactions, reactions related to the injection of DALVANCE, and an elevation of liver enzymes can also occur.

Were there any differences in side effects among sex, race and age?

Outstanding Questions

- How do we do all of this without running afoul of promotional regulations?
- How can we provide more information to patients while respecting the doctor/patient relationship, maintaining privacy, & taking blinding into account?
- What more can be done to ensure that information provided is accurate and understandable?
- How can we ensure consistency & integrity across all of the data that is made available?
- How can we all work together to answer these questions?

Thank You

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