An Imperative for Action: Patients Are Waiting

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Overview of Presentation

- Key challenges
- Congressional & media attention
- What the public says about clinical trials: implications
- Recommendations for action

“Nothing About Us Without Us”*

*A slogan originating with the South African disability movement in the early 1990’s*
Persistent Challenges in Clinical Trials

- Recruitment and retention difficulties
- Uncoordinated trial conduct—across federal agencies; across universities; globally
- Expensive, redundant data collection
- Researchers, physicians and patients interests’ and incentives not well aligned
- Physicians rarely talk about research
- Failure to include patients every step of the way—from decision to study to report-out

*Very little has changed in decades*
“Gaining an understanding of the links between science and the body politic, including the increasing demands for transparency and accountability, is fundamental to the long term success of science.”

- Introduction: “Clinical Research in the Public Eye”

21st Century Cures Act (signed into law Dec. 2016) propelled medical progress into the spotlight

- Collaborative legislative model that brought patients to the table with policymakers, researchers, industry, and other advocates, incorporating the patient voice into drug development

Sec. 3002 Patient-focused Drug Development

- FDA will issue guidance on how to collect patient experience data
- FDA will issue guidance on how relevant patient experience data and related information should be used when evaluating the risks and benefits of a drug

Sec. 3021 Novel Clinical Trial Designs

- Requires FDA to hold a public meeting and issue additional guidance assisting sponsors in incorporating adaptive designs and novel statistical modeling into NDA’s
Media is Paying Attention

A Cancer Conundrum: Too Many Drug Trials, Too Few Patients

The New York Times

THE WALL STREET JOURNAL

When Alzheimer’s hit, she joined a clinical trial. Where were the other black women?

The Washington Post

Clinical Trials Need More Subjects

By Laura Landro

Researchers conduct clinical trials to test new drugs and medical treatments, but the rate at which they are able to recruit and retain patients is at an all-time low.

Studies indicate that fewer than 10% of Americans participate in clinical trials, and only 3% to 5% of patients sign up for trials of new cancer therapies. Patients often aren’t aware that trials are an option, and their doctors may not suggest them.
The Public is Paying Attention

“...public sentiment is everything. With public sentiment, nothing can fail; without it nothing can succeed.”

President Abraham Lincoln
91% say it’s important for the U.S. to dedicate substantial funding for cancer research

73% say the U.S. should allocate more money for cancer treatment/cures, even if it means higher taxes

Source: ASCO National Cancer Opinion Survey, October 2017
Research!America Surveys

- Commissioning public opinion surveys on research issues for 25 years:
  - National Surveys
  - State-Based Surveys
  - Issue-Specific Surveys
- Online surveys are conducted with a sample size of 1000-2000 adults and sampling error of +/-3.1% to +/-2.1%. The data are weighted in two stages to ensure accurate representation of the U.S. adult population.
For most topics covered, no significant differences observed between general population and over-sampled populations.

However,

- Altruism is more likely to be a motivating factor in trial participation among minority groups than in general population.
- Minority groups are more likely to admire people who volunteer for clinical trials.
- Compared to 2013 survey, significantly fewer African-Americans, Hispanics, Asians and non-Hispanic whites say ‘lack of trust’ is a reason why individuals do not participate in clinical trials.
- Minority populations, especially African-Americans, are more likely to say people are enrolled in clinical trials without being told.
Four in Five Americans Have Heard of Clinical Trials

One kind of medical research is often referred to as a clinical trial. In this, volunteers choose to participate to test the safety and effectiveness of certain treatments, drugs or devices. Have you ever heard of a clinical trial?

Overwhelming Majority Agree Clinical Trials are Important to Nation’s Health

Do you agree or disagree that clinical trials are important to improving our nation’s health?

53% Strongly agree
34% Somewhat agree
7% Somewhat disagree
2% Strongly disagree
5% Not sure

Most Americans Have Not Participated in Clinical Trials

Have you or anyone in your family ever participated in clinical trials?

- Yes: 18%
- No: 73%
- Not sure: 9%

Most Have Not Participated in a Clinical Trial

Have you or someone in your family ever participated in a clinical trial?

7% increase among African-Americans who said ‘yes’ from 2013.

- African-American: 22% Yes, 65% No, 13% Not Sure
- Hispanic: 19% Yes, 72% No, 9% Not Sure
- Non-Hispanic White: 15% Yes, 79% No, 6% Not Sure
- Asian: 13% Yes, 83% No, 4% Not Sure

Strong Interest in Learning More About Clinical Trials

Please tell me if you agree with the following statement — I am interested in finding out more about taking part in clinical trials.

Three of Four Would Participate if Asked by Someone They Trust

Please tell me if you agree with the following statement — I would take part in a clinical trial if I was asked by someone I trust.

Awareness, Risk Top Barriers for Clinical Trial Participation

Fewer than 10% of Americans participate in clinical trials. Which of the following do you think is a reason that individuals don’t participate in clinical trials? (Check all that apply)

- Not aware/lack of information: 55%
- Too risky: 43%
- Lack of information about clinical trials process: 41%
- Lack of trust: 38%
- Adverse health outcomes: 34%
- Little or no monetary compensation: 34%
- No health conditions to treat: 24%
- Lack of access: 22%
- Too much time: 18%
- Privacy issues: 15%
- Lack of monetary compensation for physicians to discuss clinical trials with patients: 15%
- Other: 3%
- Not sure: 7%

Patients Willing to Share Health Information for a Variety of Reasons

Please indicate your willingness to share your personal health information, assuming that appropriate privacy protections are in place.

- So researchers can better understand diseases and develop new ways to prevent, treat and cure them: Yes 84%, No 6%, Not sure 11%
- To advance medical research: Yes 82%, No 8%, Not sure 11%
- So health care providers can improve patient care: Yes 79%, No 10%, Not sure 11%
- So public health officials can better track disease and disability and the causes: Yes 74%, No 11%, Not sure 15%

Opinions Split on Whether Patients Are Enrolled Without Being Told

Would you say that *without being told*, patients are sometimes included in clinical trials when they are receiving medical treatment?

- **37%** Yes
- **30%** No
- **32%** Not sure

For Minority Groups, Plurality Say Patients Are Sometimes Included in Trials Without Being Told

Would you say that *without being told*, patients are sometimes included in clinical trials when they are receiving medical treatment?

*9% increase among African-Americans and 8% increase among Hispanics who said ‘yes’ from 2013.*

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**African-American**
- **Yes**: 50%
- **No**: 21%
- **Not Sure**: 29%

**Hispanic**
- **Yes**: 44%
- **No**: 28%
- **Not Sure**: 28%

**Asian**
- **Yes**: 40%
- **No**: 30%
- **Not Sure**: 30%

**Non-Hispanic White**
- **Yes**: 31%
- **No**: 34%
- **Not Sure**: 35%

Nearly Three-Quarters Say Doctors Don’t Talk About Medical Research

Has your doctor or other health care professional ever talked to you about medical research?

Strong Majority Say Doctor Hasn’t Talked to Them about Medical Research

Has your doctor or other health care professional ever talked to you about medical research?

- **Hispanic**: 27% Yes, 67% No, 7% Not Sure
- **Asian**: 25% Yes, 68% No, 8% Not Sure
- **African-American**: 24% Yes, 68% No, 8% Not Sure
- **Non-Hispanic White**: 15% Yes, 80% No, 5% Not Sure

Doctors, Government Responsible for Educating Public

Which organizations listed below would you say have the greatest responsibility in educating the public about clinical trials? (Choose ONLY one)

- Doctors and other health care providers: 44%
- Government, for example the National Institutes of Health (NIH): 23%
- Pharmaceutical companies: 10%
- Patient organizations: 5%
- Insurance companies: 3%
- Military: 1%
- Other: 1%
- Not sure: 13%

Why aren’t health care providers talking about research?
Why are health care providers not talking about research?

- Don’t have time
- Aren’t aware of trials
- Aren’t being asked
- Don’t know how
- Fear of losing patients
- Lack of incentives
Four in Five Likely to Participate in Clinical Trials Recommended by Doctor

If your doctor found a clinical trial for you and recommended you join, how likely would you be to participate in a clinical trial?

- Very likely: 37%
- Somewhat likely: 44%
- Not likely: 7%
- Would not participate: 9%
- Not sure: 3%

Most Agree Discussion of Clinical Trials Should be Part of Standard Care

Do you agree or disagree that health care professionals should discuss clinical trials with patients diagnosed with a disease as part of their standard of care?

How important would each of the following factors be in your decision to participate as a volunteer in a clinical trial?

- Understanding potential risks and benefits: 75% very important, 15% somewhat important, 6% not very important, 6% not at all important, 6% not sure.
- Competence and reputation of people or the institution conducting the research: 74% very important, 17% somewhat important, 7% not very important, 7% not at all important, 6% not sure.
- Whether you would have medical bills covered if you had an injury from the study: 71% very important, 18% somewhat important, 6% not very important, 6% not at all important, 6% not sure.
- Opportunity to possibly improve your own health: 63% very important, 27% somewhat important, 6% not very important, 6% not at all important, 6% not sure.

How important would each of the following factors be in your decision to participate as a volunteer in a clinical trial?

- Having an expert guide you through the clinical trials process: 60% Very important, 27% Somewhat important, 5% Not very important, 7% Not at all important.
- The location of the clinical trial is easily accessible: 59% Very important, 28% Somewhat important, 6% Not very important, 6% Not at all important.
- Privacy and confidentiality issues: 54% Very important, 26% Somewhat important, 10% Not very important, 7% Not at all important.
- Opportunity to improve the health of others: 52% Very important, 35% Somewhat important, 5% Not very important, 6% Not at all important.
- Opportunity to advance scientific research: 51% Very important, 35% Somewhat important, 6% Not very important, 7% Not at all important.

How important would each of the following factors be in your decision to participate as a volunteer in a clinical trial?

1. Use of wearable health devices, mobile apps and digital technology to record your data
   - Very important: 31%
   - Somewhat important: 35%
   - Not very important: 19%
   - Not at all important: 6%
   - Not sure: 9%

2. Hearing from clinical trial participants
   - Very important: 40%
   - Somewhat important: 33%
   - Not very important: 15%
   - Not at all important: 4%
   - Not sure: 7%

3. Whether you would be paid to participate
   - Very important: 44%
   - Somewhat important: 35%
   - Not very important: 12%
   - Not at all important: 3%
   - Not sure: 4%

4. Your physician's recommendation
   - Very important: 49%
   - Somewhat important: 28%
   - Not very important: 12%
   - Not at all important: 3%
   - Not sure: 8%

How important would the opportunity to improve the health of others be in your decision to participate as a volunteer in a clinical trial?

Please rate how much you admire each of the following groups of people on a scale of 1 to 4, where 1 means you do not admire them at all, and where 4 means you admire them a great deal.

- People who donate an organ: 74% (4), 14% (3), 6% (2), 0% (1), Not sure 9%.
- People who give blood: 62% (4), 25% (3), 7% (2), 0% (1), Not sure 7%.
- People who volunteer for clinical trials: 46% (4), 34% (3), 7% (2), 9% (1), Not sure 6%.

Increase in Percent of Americans who Greatly Admire Organ Donors, Those Who Give Blood, Those Who Volunteer for Clinical Trials

Please rate how much you admire each of the following groups of people (results for respondents who said they admire them ‘a great deal’)

- People who donate an organ
  - July 2017: 74%
  - May 2013: 69%

- People who give blood
  - July 2017: 62%
  - May 2013: 61%

- People who volunteer for clinical trials
  - July 2017: 46%
  - May 2013: 37%

Source: Research!America surveys of U.S. adults conducted in partnership with Zogby Analytics in May 2013 and July 2017.
Clinical Trial Participation is as Valuable as Giving Blood

Please tell me if you agree with the following statement — Taking part in clinical trials is as valuable to our health care system as giving blood.

- 27% Strongly agree
- 48% Somewhat agree
- 11% Somewhat disagree
- 4% Strongly disagree
- 9% Not sure

It’s Time to Act

BHAGs*: Make volunteering for a clinical trial as valued as donating blood, organs or tissue.
Make regular participation in clinical research a new social norm and a routine ‘health behavior.’
Make discussing research a routine part of clinical care.

**”Big, hairy, audacious goal” - Collins, J. & Porras J. (2004). Built to Last: Successful Habits of Visionary Companies.**
Driver’s License Organ Donor Program: advocates made it happen!

- In 1969, as a result of advocacy by physicians, patients and the business community, the Tennessee Legislature passed the Anatomical Gift Act, which made it possible to donate organs.
- In 1973, Tennessee becomes first state to list organ donation as an option on a driver’s license; other states followed.
- By 2014, through the work of the donation and transplantation community in partnership with the DMV, 50 percent of the U.S. adult population, or 125 million people, were registered organ, eye and tissue donors.

Action Recommendations (1)

- Standardize and harmonize regulations: within US and globally
- End practice of every institution having unique consent form
- Learn from other nations, e.g. UK success in doubling cancer trial enrollment
- Share more data faster—across agencies, across the research ecosystem, with patients. PCORnet provides opportunity.
- Increase reimbursements to physicians for talking about research (not as a ‘bounty’ but as a routine aspect of care)
- Use new technology and social media to improve two-way communication
Action Recommendations (2)

- ‘Bring clinical trials to patients, instead of patients to clinical trials’*
- Everyone involved in the conduct of research should look for opportunities to participate in research as a volunteer themselves --experience can be a great teacher, and you will be more credible, too
- Use knowledge of concerns of special populations to design better recruitment and retention
- Address underrepresentation in clinical trials, ensuring gender and ethnic diversity
- Engage patients every step of the way-- start a conversation!

*Corsee Sanders, Ph.D. SVP, Global Head of Development Innovation & Clinical Operations, Genentech
Patient Engagement is the most important component of success!

“Gone are the days when we could just say, ‘We’re a cloistered community of researchers, and we alone know how to do this.’”

Historic effort to gather data over many years from one million or more people living in the United States

Will serve as a national research resource to inform thousands of studies, covering a wide variety of health conditions

Program is in beta testing now, with full launch in Spring 2018

https://allofus.nih.gov
NIH Appropriations in Current and Constant Dollars

Source: NIH Office of the Director, Office of Budget: http://officeofbudget.od.nih.gov/
Raise the Caps!

cqrcengage.com/ram/sequestration
A Challenge: Pass the Starbucks Test
115th Congress: Nevada Senators

Catherine Cortez Masto (D), Committee on Aging; Commerce, Science & Transportation

Dean Heller (R), Commerce, Science & Transportation
115th Congress: Nevada Representatives

Mark Amodei (R-02), Appropriations

Dina Titus (D-01), Transportation & Infrastructure

Jacklyn Rosen (D-03), Science, Space & Technology

Ruben Kihuen (D-04), Financial Services
Q: What do elected officials and scientists have in common?
Q: What do elected officials and scientists have in common?

A: Serving the public’s interest.

You can effectively start a conversation with any elected official by thanking them for serving the public’s interest. And then say how you serve the public’s interest.
Most Trusted Spokespersons for Science?

How trustworthy do you consider each of the following to be as spokespersons for science?

- Scientists
  - Very trustworthy: 40
  - Somewhat trustworthy: 42
  - Not very trustworthy: 8
  - Not at all trustworthy: 9
  - Not sure: 10

- Health care professionals
  - Very trustworthy: 25
  - Somewhat trustworthy: 54
  - Not very trustworthy: 8
  - Not at all trustworthy: 10
  - Not sure: 16

- Patient organizations
  - Very trustworthy: 15
  - Somewhat trustworthy: 51
  - Not very trustworthy: 14
  - Not at all trustworthy: 16
  - Not sure: 12

- Journalists
  - Very trustworthy: 9
  - Somewhat trustworthy: 32
  - Not very trustworthy: 31
  - Not at all trustworthy: 17
  - Not sure: 12

- Bloggers
  - Very trustworthy: 7
  - Somewhat trustworthy: 18
  - Not very trustworthy: 35
  - Not at all trustworthy: 25
  - Not sure: 15

- Business leaders
  - Very trustworthy: 7
  - Somewhat trustworthy: 26
  - Not very trustworthy: 34
  - Not at all trustworthy: 21
  - Not sure: 12

- Elected officials
  - Very trustworthy: 6
  - Somewhat trustworthy: 17
  - Not very trustworthy: 35
  - Not at all trustworthy: 30
  - Not sure: 12

And Yet, Despite High Levels of Public Confidence, Scientists are Invisible in Our Society...
Can Americans Name a Living Scientist?
Can you name a living scientist?

- Stephen Hawking (27%)
- Neil deGrasse Tyson (19%)
- Bill Nye (5%)
- Richard Dawkins (3%)
- Jane Goodall (2%)
- Anthony Fauci (2%)
- Michio Kaku (2%)
- Me (2%)
- James Watson (1%)

Do Americans Know Where Research is Conducted?
Most Americans Don’t Know Where Research is Conducted

Can you name any institution, company or organization where medical or health research is conducted?


- Mayo Clinic (17%)
- Johns Hopkins University (10%)
- St. Jude Children’s Research Hospital (6%)
- NIH (4%)
- Cleveland Clinic (4%)
- MD Anderson Cancer Center (2%)
- Harvard University (3%)
- American Cancer Society (2%)
- CDC (1%)

67% I cannot
33% I can

Zogby Analytics

Most Americans Don’t Know Research is Conducted Nationwide

To the best of your knowledge, would you say that medical research in the U.S. is conducted in all 50 states?

- Yes: 34%
- No: 28%
- Not Sure: 37%

Source: A Research!America poll of U.S. adults conducted in partnership with Zogby Analytics in January 2016.
Important for Scientists to Engage with Public on Research

How important is it for scientists to inform elected officials and the public about their research and its impact on society?

- 60% Very Important
- 26% Somewhat Important
- 7% Not Very Important
- 5% Not Important At All
- 2% Not Sure
- 2% Not Sure

Remember the most important four words a researcher can say and convey:
“I work for you.”
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