Informed Consent- Making Patient Data Count!

CAMD Informed Consent Working Group

Co-Chairs: Penny Dacks (Alzheimer's Drug Discovery Foundation) and Ann Marie Hake (Eli Lilly)

Penny Dacks, PhD (Alzheimer's Disease Discovery Foundation)

Monica Moreno (Early-Stage Initiatives, Alzheimer's Association)

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INFORMED CONSENT WORKING GROUP MEMBERS

5

BIG PHARMA

NONPROFITS

5

Member	Organization
James Hendrix	Alzheimer's Association
Penny Dacks	Alzheimer's Disease Discovery Foundation
Karen Friedman	Boehringer -Ingelheim
Mark Gordon	Boehringer - Ingelheim
Karen Morgan	Boehringer- Ingelheim
Dagmar Theis	Boehringer- Ingelheim
Steve Arneric	Critical Path Institute
Jenn Ferstl	Critical Path Institute
Volker Kern	Critical Path Institute
Debra Lappin	FaegreBD
Ann Marie Hake	Eli Lilly & Co.
Karina Bienfait	Merck & Co.
Rachel Ennis	Merck & Co.
Lisa Gold	Merck & Co.
Richard Meibach	Novartis
Elizabeth Ashford	Roche
Megan Zosch-Canniere	Roche
John Wilbanks	Sage Bionetworks
George Vradenburg	USAgainstAlzheimersDisease

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Sharing Clinical Trial Data

Maximizing Benefits, Minimizing Risk

Recommendations

- "provide … templates for informed consent for participants that enable responsible data sharing;"
- "explain to participants during the informed consent process …
  - the potential risks to privacy associated with the collection and sharing of data … and a summary of the types of protections employed to mitigate this risk, and
  - under what conditions the trial data may be shared (with regulators, investigators, etc.) beyond the trial team; …"

The NEW ENGLAND JOURNAL of MEDICINE

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Perspective

Bringing the Common Rule into the 21st Century

Kathy L. Hudson, Ph.D., and Francis S. Collins, M.D., Ph.D.

N Engl J Med 2015; 373:2293-2296 | December 10, 2015 | DOI: 10.1056/NEJMp1512205

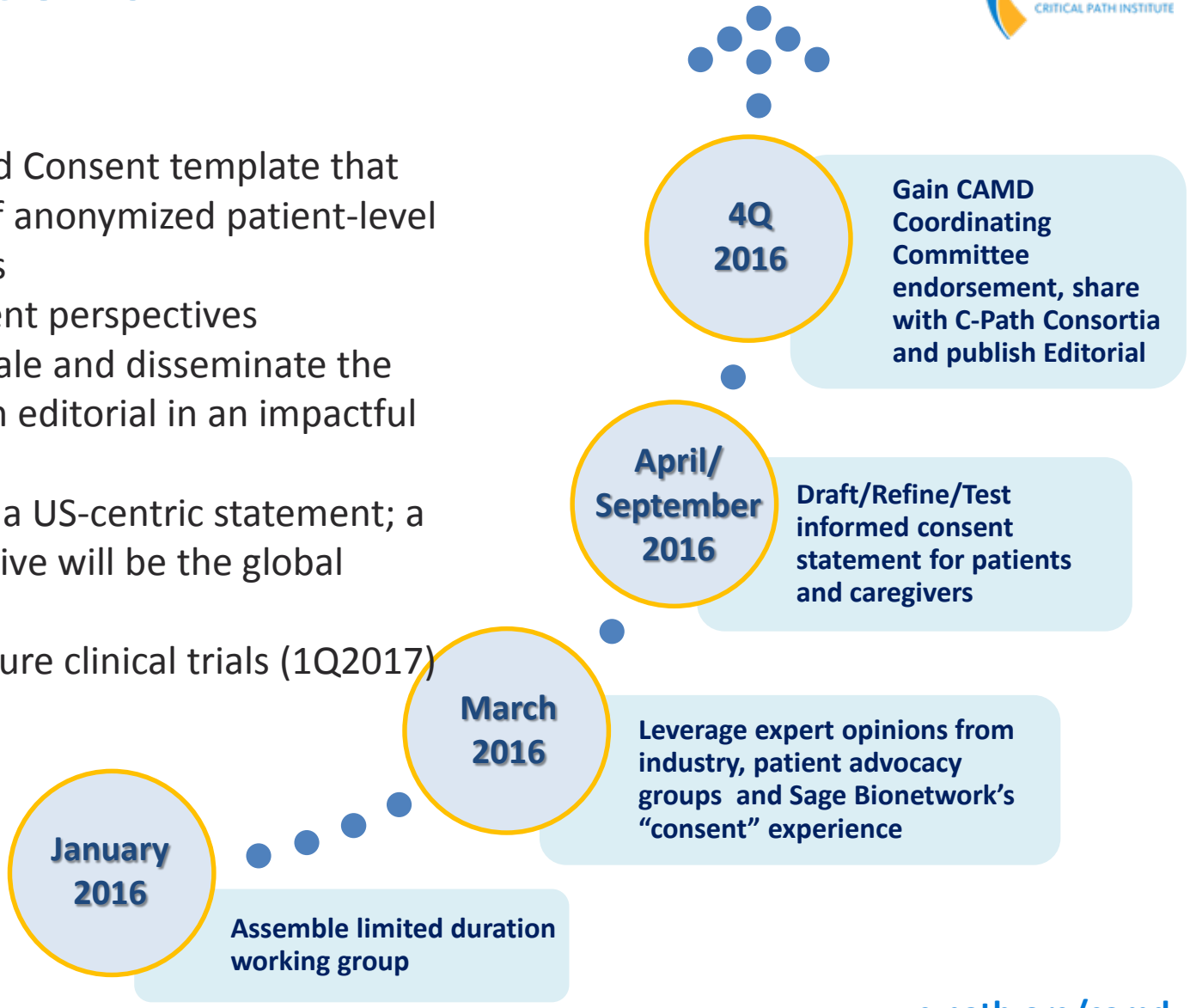
Comments open through December 16, 2015

Informed-consent documents "are too long, too complicated, and filled with legal text designed more to protect institutions than participants."

INFORMED CONSENT

Objectives

- Draft an Informed Consent template that enables access of anonymized patient-level data and samples
- Incorporate patient perspectives
- Frame the rationale and disseminate the template through editorial in an impactful journal
- Initial focus is on a US-centric statement; a secondary objective will be the global approach
- Integrate into future clinical trials (1Q2017)



INFORMED CONSENT ENABLEMENT

FULL DOCUMENT

Overview

- The information collected in this study will be used to:
  - see if the study drug works and is safe;
  - compare the study drug to other potential or approved therapies;
  - examine the relationship of the data and samples to that of other diseases;
  - develop new tests;
  - improve the design of future studies;
  - advance the understanding of health and disease;
  - accelerate other activities (e.g., creation of clinical tools that improve the delivery of innovative treatments by advancing basic and regulatory science).
- You will not be identified in any publication from this study or in any data files shared with other researchers. Your identity will be protected as required by law.
- When the information from this study is shared outside the study site, the information that identifies you will be removed. In addition, the Sponsor, like other Sponsors, provides access to clinical data that has been further de-identified so that outside researchers can use this data. Information that could directly identify you will not be included.

INFORMED CONSENT ENABLEMENT

FULL DOCUMENT -continued

Your Rights: Data & Samples

- You have the right to decide whether to participate in the study. If you decide to participate in the study, the following are groups with whom your study team may share your data and samples to improve new treatments or the conduct of clinical trials:
  - Health authorities throughout the world (e.g., Food and Drug Administration (FDA), European Medicines Agency (EMA) and other governing bodies that review clinical trials);
  - Institutions Review Boards (IRBs) that oversee, and review the ethics of the research;
  - The study Sponsor, and those working for or with the Sponsor, which may include affiliates of the Sponsor located in your country or other countries;
  - Other groups: Examples of which include academic, government or industry researchers, public-private partnerships, and/or external research collaborations. These entities will have oversight committees that will supervise the ethical use of the data and samples.
- At no time will the data or samples be allowed to be sold by an individual or group for profit.
- Your data and samples will be de-identified or anonymized. This means that your data or samples will not be linked with information that would allow any person or organization to determine that the data directly corresponds to you.
- The health information you contribute will be protected by U.S. federal law (the Health Information Portability and Accountability Act).
- New results obtained with your data and samples will be reported back to the sponsor, and the results made publically available.
- You have the right to withdraw your permission for us to use or share your information up until the time that your data and samples are de-identified and pooled together into a database. Your data and samples will be used and shared as described in this form.

INFORMED CONSENT ENABLEMENT

FULL DOCUMENT -continued

Potential Benefits & Risks

Benefits

Allowing your de-identified data and samples to become available to research and regulatory organizations could advance new treatments. By giving approval now for your data and samples to be shared for research purposes, your valuable contributions have the best chance to be used as effectively as possible for research not only today, but also in the future as new research questions and technologies emerge.

Risks

Your de-identified or anonymized data may be shared for research purposes. Because your data and samples are de-identified (anonymized), the potential is extremely small that a person or organization could determine that it belongs to you. However, anonymity cannot be absolutely guaranteed. Experts in re-identification may in very rare cases be able to reverse the processes used to protect your identity and confidentiality.

Withdrawal of Consent

I understand I can withdraw permission to collect data/samples at any time but data already collected and pooled into the database will continue to be used. The study doctor/staff will discuss this with you.

Consent

I give permission to use and share my data and samples as described in this document.

2. SHORT VERSION (TO EXPAND FUTURE USE OF DATA & SAMPLES)

Use of Data and Samples for Additional Research Outside of this Clinical Trial

Your Rights: Data & Samples

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  - Health authorities throughout the world (e.g., Food and Drug Administration (FDA), European Medicines Agency (EMA) and other governing bodies that review clinical trials);
  - Institutions Review Boards (IRBs) that oversee, and review the ethics of the research;
  - The study Sponsor, and those working for or with the Sponsor, which may include affiliates of the Sponsor located in your country or other countries.
  - Other groups: Examples of which include academic, government or industry researchers, public-private partnerships, and/or external research collaborations. These entities will have oversight committees that will supervise the ethical use of the data and samples.

SHORT VERSION FINAL-continued

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Consent

I give permission to use and share my data and samples as described in this document.

Informed Consent: The Patient Perspective

Monica Moreno
Director, Early-Stage Initiatives

alzheimer's association®

National Early-Stage Advisory Group

Advance the cause Alzheimer's throug

- ✓ Awareness Initiatives
- ✓ Advocacy
- ✓ Programs

Role:

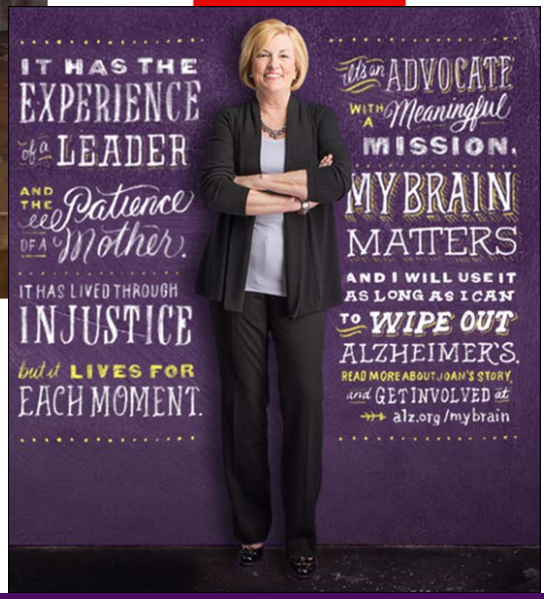
- Spokesperson
- Advisor
- Presenter/Keynot speaker

Commitment:

- One year term

Raising Concern and Awareness

> *Thank you thank you very very much for EVERYTHING. Love you so much. Julie.*
>
> **Julianne Moore's text to Sandy Oltz**



National ESAG Media Placements

ESAG Engagements

Appointments	Provided Comment On	Presentations
• **FDA** Patient Representative Program • **NAPA** Advisory Council on Alzheimer's Research, Care and Services • **FDA** Patient Engagement Advisory* Committee* • **Medicare** Beneficiary Council (CP)	• Behavioral Risk Factor Surveillance System **(BRFSS)** • Shared Decision Making Tool **(AAN)** • Practice Guideline on the Use of Antipsychotics to Treat Agitation & Psychosis in Patients with Dementia **(APA)**	• Social Security Administration (SSA) • **FDA** Division of Neurological & Physical Medicine Devices • **Office of Minority Health** Bilingual Twitter Chat: Latino's and Alzheimer's disease (Hispanic Heritage Month) • Society for Nuclear Medicine & Neuroimaging **(SNMMI)** • American Society of Neuroradiology **(ASNR)**

Informed consent review

- 2016 ESAG
  - Dx:
    - Alzheimer's, Lewy Body Dementa, MCI
  - Age: 52 to 81
- Discussion held at in-person meeting in Chicago, IL
- Conference call with nine care partners

Informed consent discussion

Overall participants enthusiastically supported the development of a consent form as a necessary document to further clinical trial research through collaboration.

- *"To me this is a no brainer. I am just learning now that this data was tossed out the window. I am shocked."*

- *"I am getting emotional. It makes me angry to think that they could be using this [data] to find a cure."*

Informed consent discussion

Agreement among both groups that the gains for the future sharing of critical patient level information and accompanying samples outweigh any potential risks

"You always run a risk that your data or info will escape, but if it will further the cause of finding a cure/treatment, I think the benefit outweighs the risk"

Withdrawal of consent

Consensus among individuals living with dementia and care partners:

Withdrawal of consent would only be effective at the time of the request and any information from the data/samples already shared would not be eligible for withdrawal

"*Because of the nature of this disease, if I don't remember everything I signed, yet I knew I wanted this at the time, I don't want someone (POA) to change this decision.*

Informed consent - Primary concerns

- Ethical standards
- Protection of identity
- Protection from samples/data being sold for economic gain by individual or company
- Building trust among minority groups

"I don't think anyone protects information better than an ethical research organization."

Importance of engaging people living with the disease

Understanding the experience of those living with Alzheimer's disease is paramount to:

- developing more effective treatment strategies
- offering effective care and support programs
- learning how to better enhance quality of life
- meet the needs present today
- prepare for the needs of those not yet affected

Thank you!

Monica Moreno
mmoreno@alz.org

Monica Moreno
Director, Early Stage Initiatives

alzheimer's association®

INFORMED CONSENT WORKING GROUP SUMMARY (US- Centric):

- ✓ Identification of Working group Co-Chairs (April 18, 2016 meeting)
- ✓ Have John Wilbanks frame eConsent and the work that Sage BioNetworks has initiated (March)
- ✓ Convened a focus meeting (1/2 – full day) to develop a draft informed consent document (April 18, 2016)
- ✓ Complete draft with feedback from members legal departments (June 17, 2016) & receive input from PWD and their Caregivers (August)
- ✓ Gain Coordinating Committee endorsement to integrate into future clinical trials October 5, 2016
- ✓ Frame the rationale for improving informed consent and disseminate the template through an editorial in a prominent journal
- Submit by end of 4Q16

DRAFT INFORMED CONSENT STATEMENT

Next Steps:

- **Create Editorial (November).**
- **C-Path Consortia interested in reviewing (November):**
  - **CPP** – Critical Path for Parkinson's
  - **MSOAC** – Multiple Sclerosis Outcome Assessment Consortium
  - **D-RSC** – Duchenne - Regulatory Science Consortium

NEXT STEPS

Develop Ex-US version (2017)

1. (1Q17) Have Alzheimer's Disease International provide feedback on the US-centric document to gauge potential challenges
2. If encouraging, proceed with Ex-US version
3. If not, revisit the what would provide the best return on investment of time & effort

Retrospective Reviews on Informed Consent

If participants were not informed about data-sharing, what would they assume?

- "Must respect the 'spirit of the informed consent' as seen through the eyes of the participant – What would a reasonable person assume?"
  IOM Presentation by Pearl O'Rourke, Partners HealthCare
- A patient perspective: *"To me this is a no brainer. I am just learning now that this data was tossed out the window. I am shocked."*
- "There is an ethical obligation to responsibly share data generated by interventional clinical trials because participants have put themselves at risk." International Committee of Medical Journal Editors (ICMJE), Taichman *et al., JAMA*, February 2016

Thank you!

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