



Unlock Value. Manage Risk. Innovate.

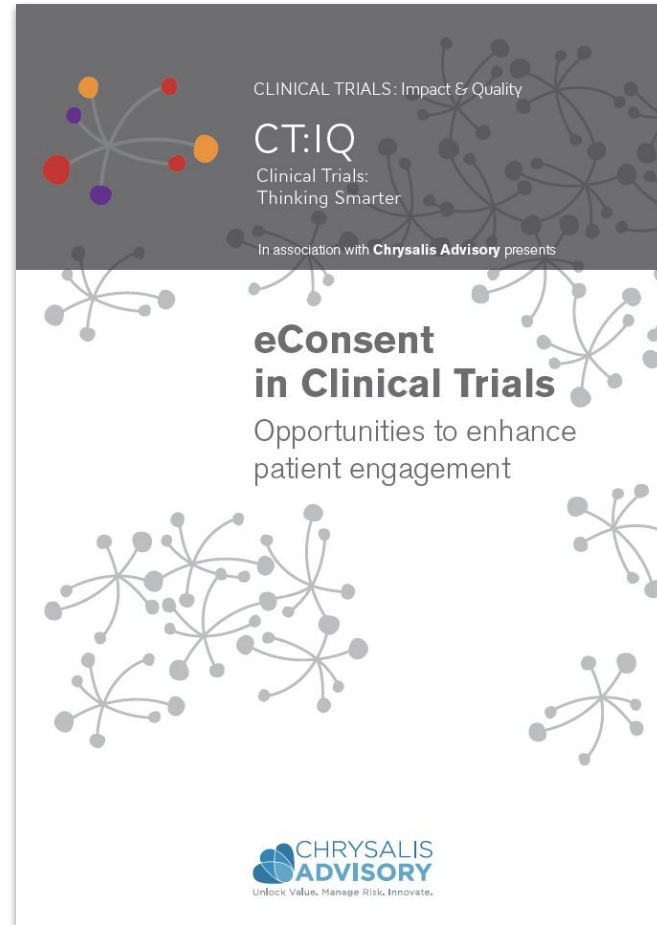
# eConsent in Clinical Trials

Opportunities to enhance patient engagement

CT:IQ Steering Committee, 24 June 2019

# Agenda

- 01 | Project scope
- 02 | Methodology
- 03 | Background & context
- 04 | Use cases
- 05 | Benefits
- 06 | Barriers to uptake
- 07 | Pathways forward - critical success factors



# 1. Scope

The purpose of this CT:IQ project was to investigate barriers to uptake of eConsent within the Australian clinical trial context and create actionable insights to support increased adoption of the technology. In addition, gaining a greater understanding of the current use and adoption of eConsent across the Australian clinical trials landscape, including stakeholder opinions about the benefits, risks and critical success factors for eConsent implementation, provides information for those seeking to trial and ultimately implement eConsent.

## 2. Methodology

- Semi-structured interviews with 19 stakeholders
- Survey questionnaire, n = 179

### 3. Background & context

What exactly do we mean by eInformation and eConsent?

# How much exposure to eConsent have people had?

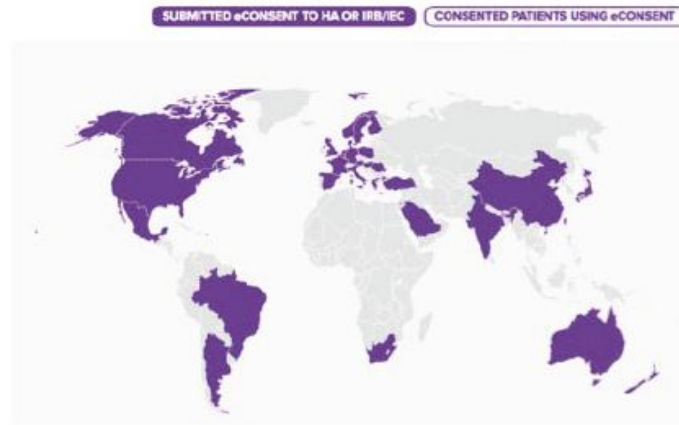
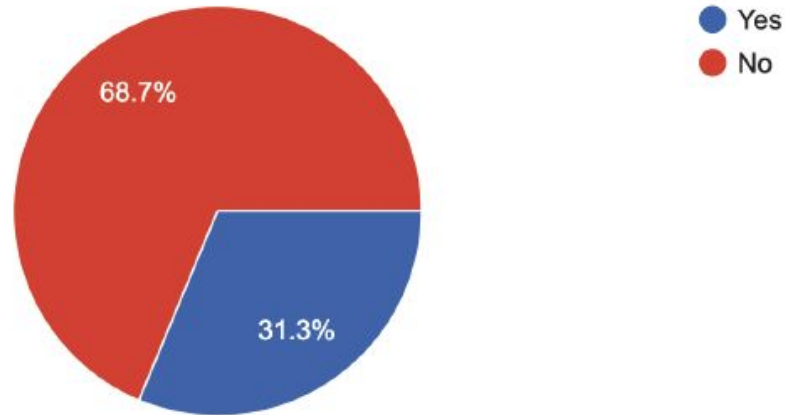


Image Source: TransCelerate Landscape Assessment © 2017

No 1

**Have you ever been involved in a clinical trial with eConsent processes (in any context, eg as participant, site staff, sponsor, CRO, clinician)?**

179 responses



## 4. Use Cases

- 1 eConsent with a physical signature
- 2 eConsent on a supplied device

- 3 eConsent using cloud-based software
- 4 eConsent using biometric information



## Longer Consent Forms for Clinical Trials Compromise Patient Understanding: So Why Are They Lengthening?

**TO THE EDITOR:** Participation in cancer clinical trials is essential to ensure ongoing improvements in the management of people diagnosed with cancer. It is generally accepted that subjects in a clinical trial should understand a minimum amount of information to provide informed consent. Understanding the diagnosis, prognosis, nature and purpose of the intervention, alternatives, and risks and benefits are generally considered essential. Patient information and consent forms (PICFs) are an important part of communicating this information. Despite this, patient knowledge and adequacy of informed consent to clinical trials has been demonstrated to be suboptimal.<sup>1,2</sup>

We performed a study to assess knowledge and satisfaction regarding the informed consent process concerning cancer clinical trials.<sup>2</sup> Our team studied a convenience sample of 102 patients, participating in 27 therapeutic clinical trials across four hospitals. Part of this study involved a review of the PICFs. The forms were

**Table 1.** Information Frequently Missing From PICFs

Type of Information	PICFs Missing Information (%)
Basic information	
Specific cancer being studied	12
Reason for research	12
Patient's right to receive a copy of PICF	12
Notice of voluntary participation	6
Options and further discussion	
Suggestion to discuss participation with family	35
Other treatment options available	12
Suggestion to discuss all options with doctor	24
Risks	
Potential for sterility	29
Irreversibility of risks	26
Financial impact	
Participation is not compensated	35
Suggestion to discuss additional costs with doctor	53
Possibility of having to pay for the drug if it becomes commercially available	94

Abbreviation: PICFs, patient information and consent forms.

# Current usage of eConsent/Patient Registration

A cluster randomised, crossover, non-inferiority trial of aspirin compared to low molecular weight heparin for venous thromboembolism prophylaxis and safety in hip or knee arthroplasty, a registry nested study -CRISTAL (ACTRN12618001879257)

Prof Ian Harris- UNSW

- Consent is to the data collection
- Pragmatic design of SOC options
- Patients can register either through a URL or an iPad
- Questionnaires delivered through URL, iPad or through telephone interview.



# HHS Public Access

Author manuscript

*Comput Inform Nurs.* Author manuscript; available in PMC 2018 November 01.

Published in final edited form as:

*Comput Inform Nurs.* 2017 November ; 35(11): 556–564. doi:10.1097/CIN.0000000000000356.

## User-centered Design, Experience, and Usability of an e-Consent User Interface to Facilitate Informed Decision Making in an HIV Clinic

S. Raquel  
Postdoctoral  
Connecticut

More than half of the study population had college experience, but challenges remained with overall comprehension regarding consent. The user interface was not independently successful, suggesting that in addition to an electronic consent user interface, human interaction may also be necessary to address the complexities associated with consenting to electronically share health information.

Comprehension is a key factor in the ability to make informed decisions.



OPEN

## Data Descriptor: The asthma mobile health study, smartphone data collected using ResearchKit

Yu-Feng Yvonne Chan<sup>1,2,3</sup>, Brian M. Bot<sup>4</sup>, Micol Zweig<sup>1,3</sup>, Nicole Tignor<sup>1,3</sup>, Weiping Ma<sup>1,3</sup>, Christine Suver<sup>4</sup>, Raffhael Cedeno<sup>1,3</sup>, Erick R. Scott<sup>1,5</sup>, Steven Gregory Hershman<sup>6,7</sup>, Eric E. Schadt<sup>1,3,5</sup> & Pei Wang<sup>1,3</sup>

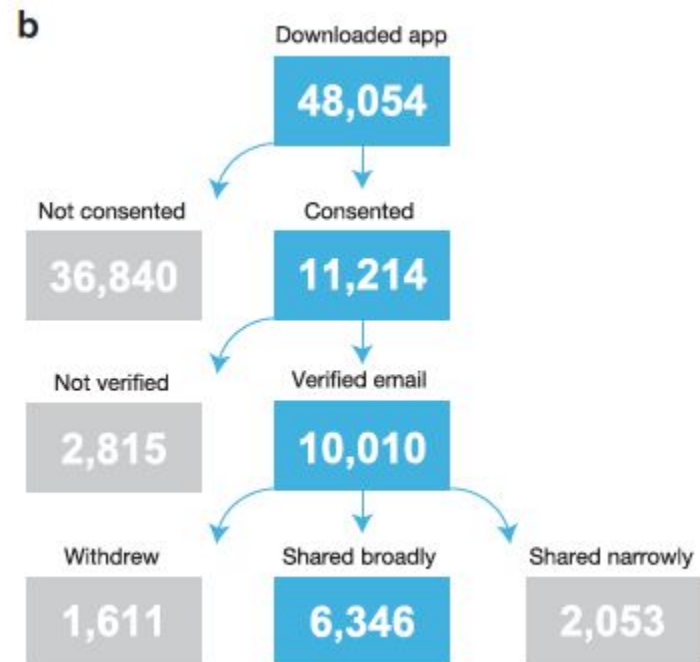
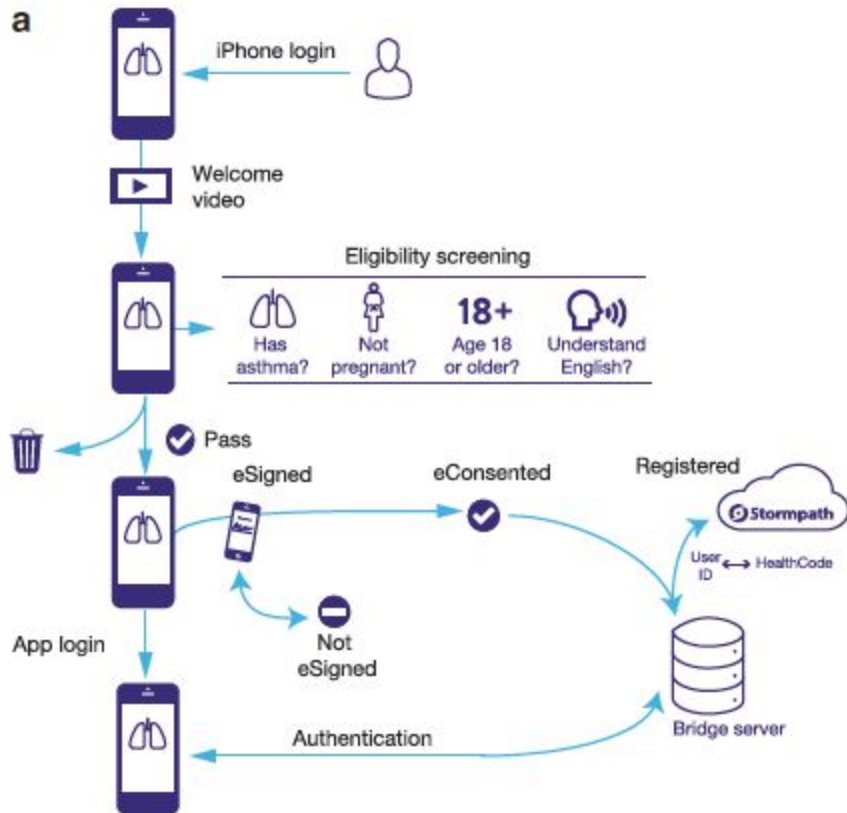
Received: 14 July 2017

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Published: 22 May 2018

Widespread adoption of smart mobile platforms coupled with a growing ecosystem of sensors including passive location tracking and the ability to leverage external data sources create an opportunity to generate an unprecedented depth of data on individuals. Mobile health technologies could be utilized for chronic disease management as well as research to advance our understanding of common diseases, such as asthma. We conducted a prospective observational asthma study to assess the feasibility of this type of approach, clinical characteristics of cohorts recruited via a mobile platform, the validity of data collected, user retention patterns, and user data sharing preferences. We describe data and descriptive statistics from the Asthma Mobile Health Study, whereby participants engaged with an iPhone application built using Apple's ResearchKit framework. Data from 6346 U.S. participants, who agreed to share their data broadly, have been made available for further research. These resources have the potential to enable the research community to work collaboratively towards improving our understanding of asthma as well as mobile health research best practices.





Lastly, we observed significant decline in study retention over time. As discussed in Chan *et al.*<sup>4</sup>, the observed dropoff in user retention is shared by multiple ‘digital’ use cases (e.g., mobile apps including entertainment ‘gaming’ apps, tutorial videos, open online courses) and thus suggests the biopsychosocial tendencies and behaviors of users may be hardwired. Given the ultimate goals of digital health generally rely on prolonged participation, the creators of these tools must devote attention and resources to incorporating psycho-social and behavioral principles in digital health design beyond technical ones. One consideration is to offer financial incentives for study participation to enhance retention- which is standard practice in clinical research<sup>9,10</sup>.

# CALD

## Asia-Pacific Journal of Clinical Oncology

### ORIGINAL ARTICLE

## Lower trial participation (CALD) cancer patients

Allan 'Ben' Smith ✉, Meera Agar, G  
Jennifer Aung, Pinky Patel, Nasreen

First published: 30 October 2017 |

**Funding Information:** Cancer Instit  
13/TRC/1-01; University of New Sout  
Illawarra Shoalhaven Local Health D

### Results

A total of 19 453 patients were analyzed (54.9% non-CALD, 16.5% CALD-PLNE, 18.5% CALD-PLNE). Overall, 7.4% of patients were enrolled in a trial. Trial participation was significantly lower in CALD patients than non-CALD patients (5.7% vs 8.4%; odds ratio [OR] = 0.80; 95% confidence interval [CI], 0.69–0.91;  $P = 0.001$ ). CALD-PLNE patients were less likely to participate in trials than non-CALD (OR = 0.45; 95% CI, 0.36–0.56;  $P < 0.0001$ ) and CALD-PLNE patients (OR = 0.53; 95% CI, 0.67–0.41;  $P < 0.0001$ ).

### Conclusions

Limited English proficiency seems particularly unfavorable to trial participation. Development and evaluation of strategies to overcome language barriers (e.g. simplified and translated multimedia participant information materials) is needed.

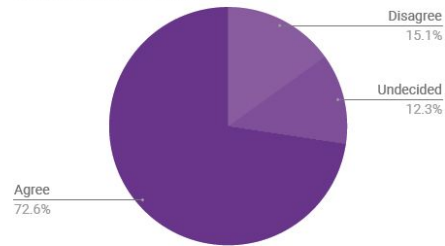
# Regional and Rural patients

- Teletrials still not widespread and won't be achievable for all studies
- Patients will require stays in metropolitan centres
- Eligibility screening and consent can be done remotely
  - Pre-reading may reduce time needed to go through the consent process- which may reduce the stay away from home
  - New information can be shared more easily

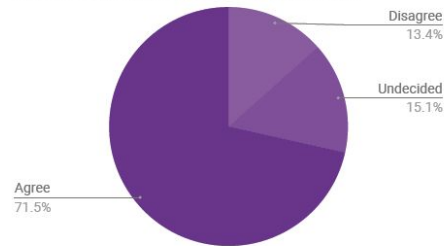


## 5. Benefits

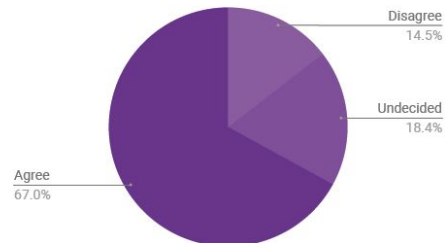
Anywhere, anytime access



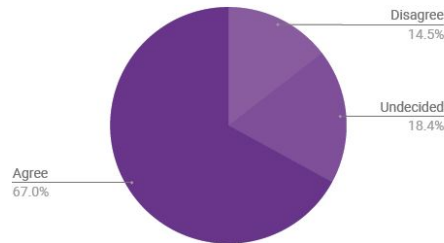
Easier data access for monitors and audits



Better version control

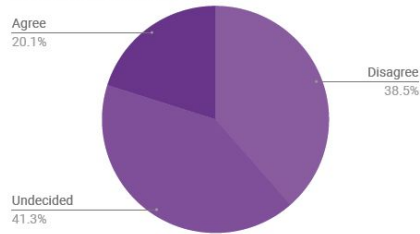


Better patient understanding due to ability to use multimedia

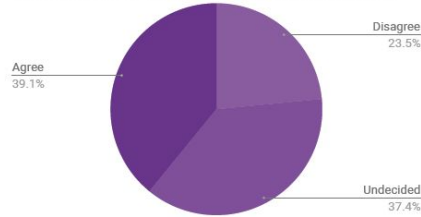


# What wasn't seen as a significant benefit?

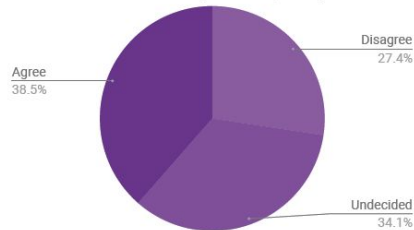
Increased patient retention



More effective dialogue between clinician and patient

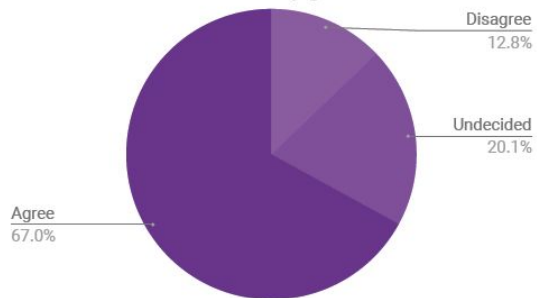


Increased conversion of potential participants

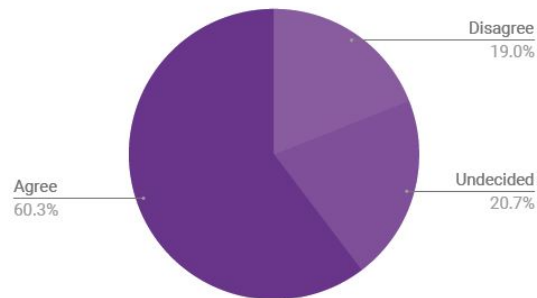


## 6. Barriers to uptake

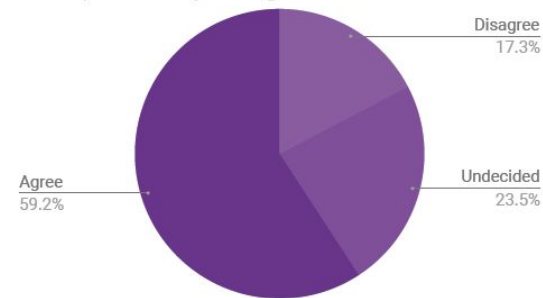
Lack of standardised industry guidance



Initial cost

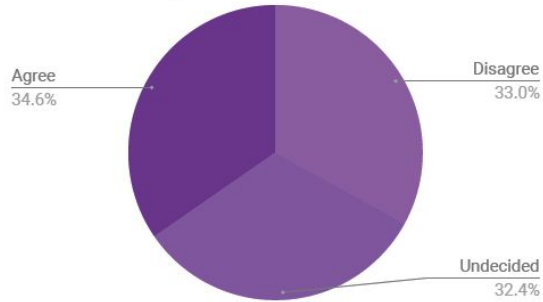


Participant identity management

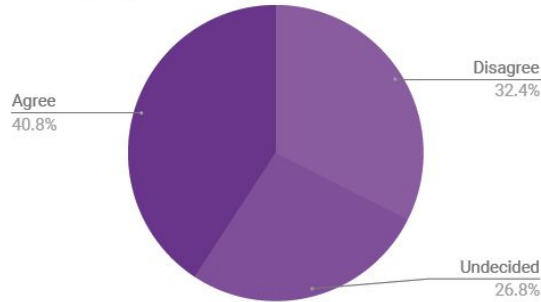


# What wasn't seen as a significant barrier to uptake?

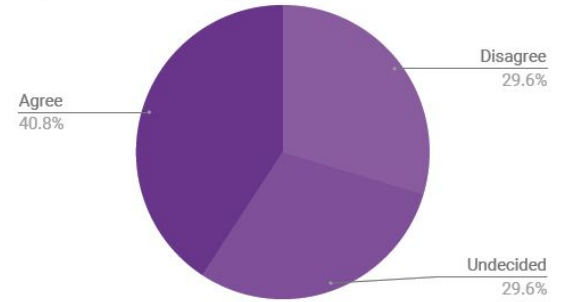
Risk of non-compliance



Inability to get HRECs approval

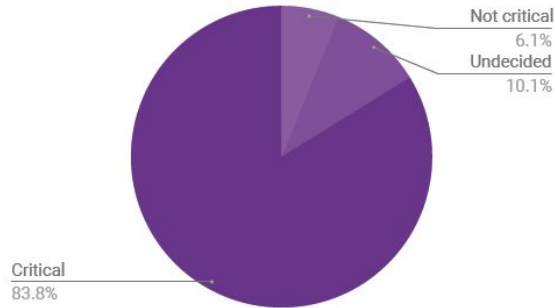


Duplication of existing processes

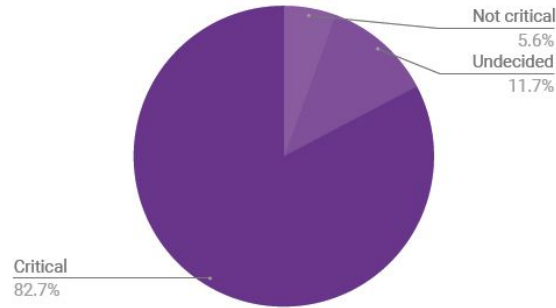


## 7. Pathways forward - critical success factors

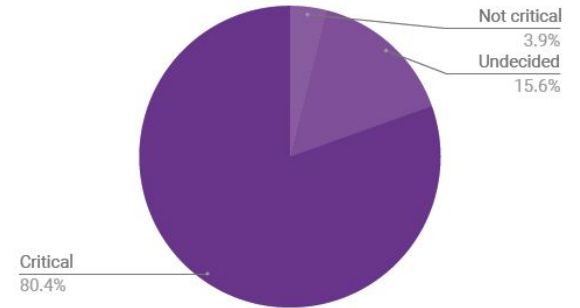
Pilots of e-consent to show evidence



Site IT capability & infrastructure

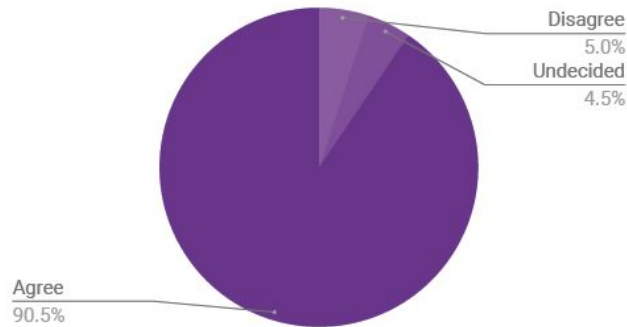


Education & training

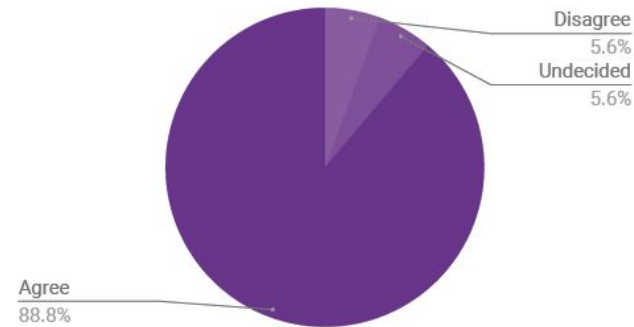


## 7. Pathways forward - critical success factors

Guidelines are required for Sites



Guidelines are required for Ethics Committees



# Open Forum Questions

1. What questions do people have?
2. Where to from here?
3. How might CT:IQ help to catalyze change and support adoption of eConsent?



# Thank you.

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