

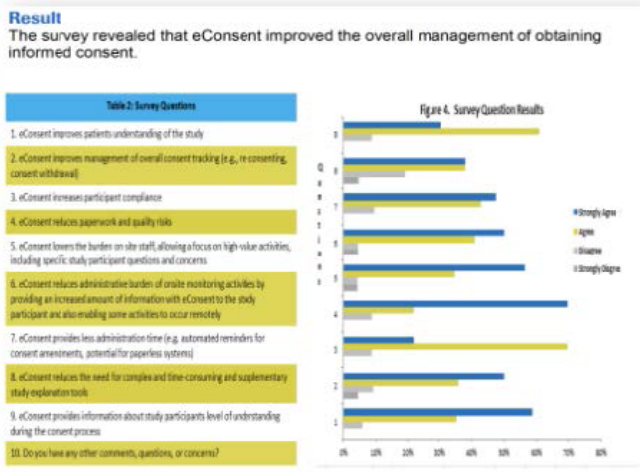
Informed Consent with Rave eConsent

While the shift to digitizing the clinical trial process is underway, the informed consent process for clinical trials generally has been paper-based. With the exponential number and increasing complexity of clinical studies now being run the paper-based informed consent process is inherently inefficient. The benefits of eConsent include an ability to provide patients clear and easy-to-understand clinical trial information, improved patient compliance, a reduction in inspection findings and enable process efficiencies.

Rave eConsent is an innovative, patient-friendly, electronic informed consent and patient enrollment system for clinical trials. Through the use of multimedia technology, patients are educated and guided through key elements of a clinical trial. eConsent can be used for clinical study consents, assents, disease registries, biobanking registries. eConsent allows the patient, sites, CRO and sponsor a unified experience for enrollment while providing additional study analytics to the site and CROs.

eConsent Reduces Burden and Risk

Sites report a significant decrease in the administration burden for managing the consent process, handling reconsent, and reporting.¹ Quality risks such as missing documents, wrong documents, missing signatures, missing or wrong dates were also reduced.



¹ The use of Electronic Informed Consent (eConsent) in a Blood Collection Study-Pilot Study; Roche Molecular Systems

PATIENT CLOUD

Single, Unified Clinical Platform

Capture, track, analyze, visualize, and report on all types of patient-centered clinical trial data whether in the clinic or remotely.

Operational Scale

We see a future where the inclusion of mobile technology is no longer a question for operational teams.

Any Study, Anywhere

Global clinical trials require flexible solutions that can meet evolving study requirements, local regulatory guidelines, and can be deployed on a variety of hardware and in a variety of shapes and styles.

A Larger Journey

A new set of workflows revolve around the patient, providing profound new experiences for clinical trials.

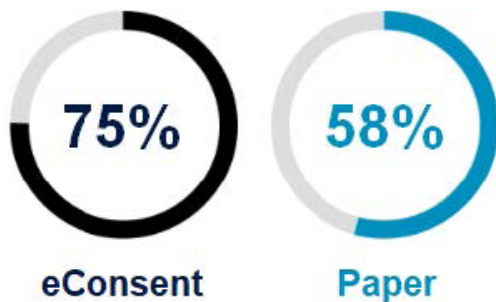
PATIENT CLOUD PRODUCT LINE

Medidata's Patient Cloud is a suite of products including: Rave eConsent, Rave eCOA, Rave Wearable Sensors, and Rave Virtual Trials.

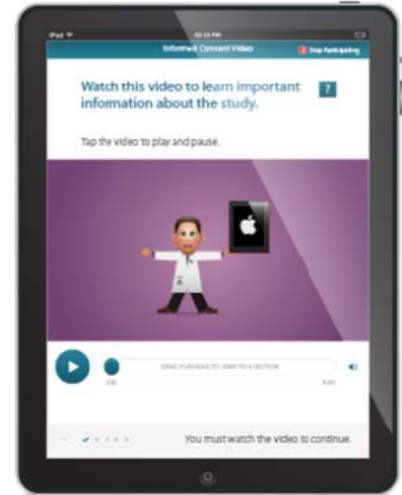
eConsent Allows Patients to Learn

Patients that use eConsent have a better understanding of the study purpose, risks, benefits, schedules, and their rights and responsibilities than patients using just paper. A better informed patient is statistically more likely to participate in a clinical study.

Superior Comprehension



*2013 Independent Validation Study
Conducted by California Pacific Medical
Center Research Institute Using eConsent*



eConsent is Industry Supported

Regulatory agencies, ethics committees, sites, sponsors, and CROs



“Electronic processes to obtain informed consent may use an interactive interface for the informed consent process, which may facilitate the subject’s ability to retain and comprehend the information.”



“Current informed consent practices make it challenging to meet the ethical obligation to adequately inform potential research participants.... eConsent can serve these purposes by including elements that aid understanding of clinical research and study participation, in addition to the information provided in a paper ICF.”



“The ethical goals of informed consent and the importance of considering research context should guide us as we assimilate technology into research and the informed consent process and develop creative and effective evidence-based practices”

Rave eConsent Features and Benefits

SETUP

Rave eConsent is delivered “as-a-service” for your clinical trial, with no infrastructure required by the sponsor or sites except for a wireless network connection. Medidata will work with each site to ensure connectivity and application function prior to your first patient visit.

DIRECT INTEGRATION

If you have Rave EDC, you can integrate directly with iMedidata and Rave RTSM for Single Sign On, creating subjects and randomization.

CONFIGURE

Decreases eConsent study and site set-up timeline from months to weeks. Configuration eliminates manual setup and duplicate work. Using a document template you can easily import existing site configuration to a newly added site all with direct unification of study and site master data.

TRAIN

Online or onsite training is provided for every project, including full user guides, on-demand training videos and personalized support. Sites, Sponsors, CRO's, and Monitors all receive training on the eConsent platform to ensure that participants are properly enrolled.

SCREEN

Providing educational study materials on the eConsent Patient Portal, sites are able to pre-screen potential participants before they arrive at the study site to ensure that the study is the right match for the participant and visa-versa.

CONSENT

eConsent provides secure, compliant electronic informed consent that leads potential participants through the informed consent process, using scientifically tested methods to ensure a greater level of comprehension.

About Medidata

Medidata is leading the digital transformation of life sciences, creating hope for millions of patients. Medidata helps generate the evidence and insights to help pharmaceutical, biotech, medical device and diagnostics companies, and academic researchers accelerate value, minimize risk, and optimize outcomes. More than one million registered users across 1,400 customers and partners access the world's most-used platform for clinical development, commercial, and real-world data.

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