eConsent Initiative

eCONSENT: EMERGING TRENDS AND FUTURE CONSIDERATIONS

TransCelerate BIOPHARMA INC.
ACCELERATING THE DEVELOPMENT OF NEW MEDICINES

Foreword

This document is intended for sponsors and other interested stakeholders to introduce and facilitate the implementation of eConsent. Every company is free to decide and must decide for itself whether, to what extent, and in what manner to implement eConsent and to rely on the guidance set forth herein. This Guidance merely is intended to help those companies that decide to adopt eConsent to do so in an efficient and effective manner. It is not intended to provide specific standards or specific guidance directed to sites or vendors, or specific regulatory references. It does not provide specific guidance to the content of informed consent or the process of administering informed consent.

Disclaimer: Nothing in this document constitutes legal advice. Users are responsible for ensuring their own compliance with all applicable laws and regulations in the jurisdiction in which they are conducting the research, associated with the informed consent process. Any party using this document bears sole and complete responsibility for ensuring that any materials or programs developed or any actions undertaken as the result of its use complies with all applicable laws and regulations.

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eConsent: Emerging Trends and Future Considerations

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2 Abbreviations

EHR	electronic health record
EU	European Union
IEC	independent ethics committee
IRB	institutional review board
IVRS	interactive voice response system

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3 Emerging Trends and Future Considerations

Technological innovation is ongoing and may impact all aspects of clinical studies. eConsent is one of many innovations that are part of the participant experience and importantly is often the first interaction the participant has with the clinical trial process. Beginning with eConsent, sponsors can engage participants through personalized portals where information may be individually tailored. eConsent may serve to support a rich study participant experience throughout the clinical study and beyond.

> *"There are two areas of focus regarding patient centricity in research: patient centeredness and patient engagement. Patient centeredness is defined as research that is based on outcomes that are important to patients. Patient engagement in research is the active participation of patients throughout the entire research process – the planning, the conduct and the dissemination. Patient engagement is the means to the patient centeredness."*
>
> *– Sue Sheridan, Director of Patient Engagement, Patient-Centered Outcomes Research Institute (PCORI).*

Informed consent is fundamental to patient-centered care. Involving study participants in their care requires that they are fully informed and electronic, patient-guided technologies will have a significant effect on evidence-based medicine. eConsent is a basic building block in a growing technology environment focused on providing individuals with control over the robust exchange of their health information with health-literate content. Some consumers use portals, including electronic health records (EHRs) supported by medical practitioners and commercial sites provided by insurers, advocacy groups, and patient communities. The future offers an opportunity to create an electronic environment that integrates patient-related information from disparate healthcare providers thus enhancing the participant's connection to clinical studies, optimizing information sharing during the consent process, and enhancing participant engagement throughout the study. Ensuring robust security and controlling access allows the sponsor and the site to gain significant efficiencies and reduce effort and cost associated with current consent processes.

3.1 Emerging Trends

The ever-increasing complexity of partners participating in healthcare, combined with a growing globalization and mobility of our population, is driving the need for

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an economical and efficient means of bringing information together to facilitate decision-making. Increasing sophistication of data analytics in health information management will enable information mining from consent tools to improve the participant's experience and save money. Data sharing, which currently entails consents with multiple partners, high cost, and time-consuming efforts, may be simplified, granting increased autonomy to the patient. Some emerging technological trends relevant to eConsent are summarized in Table 1.

Table 1 Emerging Trends Related to eConsent

Trend	Advantages
Integration with study operational systems	Fewer technology interfaces would simplify working across systems; currently multiple different systems may be a disincentive
Flexible device approach	Allowing participants to bring their own devices can improve access and autonomy
Mutual training recognition	Consistent tool-based training would reduce redundant work for sites and sponsors
Efficient authoring and approval	New software could allow collaboration between the sponsor and IRBs/IECs during consent authoring and approval
Improved data sharing	Connecting eConsent with IVRS and clinical laboratory databases would reduce data transcription errors

3.2 Supporting the Participant Throughout the Study

This integrated health information exchange of the future may also support participants' ability to make real-time choices about their participation and to modify those choices both during and after the study. Participants could also be connected to advocacy and patient groups to allow sharing with other individuals undergoing the same or similar treatment and challenges. Applicable privacy laws must be considered, including the assurance that the participant has appropriately consented to have their information shared/stored.

Participation in a clinical study through a centralized database would greatly simplify participant engagement. Industry, academic, and government resources could co-sponsor and fund this centralized database to match studies and consents. This would eliminate much redundant infrastructure, reduce noncompliance due to multiple study participation, build broader transparency into research, and expose participants and their healthcare practitioners to the best options across research sponsors.

Advantages to a study participant portal could include, if the participant consents:

- Access study information, receive payments, be notified of visits, and access their own study data

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- Receive more information about their condition and treatment alternatives based on study data from related private or commercial sources
- Maintain contact, outcomes research, and follow-up questions in a structured format designed for analysis
- Receive standard clinical laboratory results, and possibly aggregated data to support exploratory or future research with samples or data collected in clinical studies
- Receive information about new proposed research

In the future, eConsent and clinical study offerings could be centralized in an externally hosted location for prospective and active study participants. This could result in a global standard for clinical study information allowing the creation of a master list of all approved clinical studies. Use of this master list with eConsent would support programmatic matching of participants and studies based on information in their EHR or a series of online questions answered by a prospective participant or healthcare provider.

3.3 Combining Healthcare with Clinical Studies

Future studies could involve online prescreening. Once an individual has participated in an eConsented study, study enrollment criteria could be assessed against a prospective participant's record, if appropriate under applicable privacy laws. This would increase autonomy for the participant, allowing proactive seeking out of studies better suited to the individual and/or the choice to share EHRs to see if they may be eligible to participate in studies. This could eventually be automated within a shared health IT environment. Integration of health records together with eConsent would also make it easier for investigators to decide whether a specific study is appropriate for a specific patient, and eventually provide an option for study participants to consent on their own, outside of the regular clinical study process. This could be especially beneficial in supporting future-use sample testing where re-consent can often be rate limiting.

Once a prospective participant is linked to one or more clinical studies, prospective participants could review and select the study and the participating clinical site that would be best suited for them. The potential participant could then review the critical elements of the specific informed consent for the study, including the risks, benefits, time commitments, and costs. Such upfront engagement could be at the participant's convenience and would promote a more robust conversation with the clinician during the formal consent for the study, improving the participant experience overall.

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3.4 Optimizing Information Sharing During the Consent Process

Integration of eConsent with the EHR would also be valuable because a site or sponsor could programmatically confirm that a potential participant is not already enrolled in another concurrent study. Concurrent study participation can easily be missed in today's siloed technology environment. When found, it can be very costly, particularly when procedures and sample analysis have already begun. Integration of eConsent with the EHR could also reduce redundant testing by coordinating standard-of-care testing with planned research testing. Integration of insurer information would better inform potential study participants about the costs of participating in a study. Both the principles of informed consent and of patient-centric healthcare would be well served by such a user-centric application to provide more information about the requirements of participation. Improved transparency of clinical trial participation with the patient's EHR would be another important benefit, leading to a more seamless and coordinated health response involving the primary care physician, a clinical study investigator, and other healthcare practitioners.

3.5 Closing Thoughts

Some of these future considerations may be realized soon and may require significant advancement in both technology and change readiness across all participants in the healthcare IT infrastructure. These future potential changes may provide opportunities that include but extend beyond eConsent. Industry can expedite and lay the necessary foundation for an environment that facilitates increased use of patient-centric technologies in clinical trials, such as eConsent, by supporting technological advancements such as the following:

- Patient portals connecting eConsent, study information, training, results, study information, and other interactive participant engagement technologies
- Harmonized metadata for studies and consents that would promote global access to treatment options
- Common clinical study research result portal to deliver aggregate results of exploratory research, clinical study outcomes, and future research consented through both traditional and electronic means

Imagining a future for eConsent inspires a broader array of digital engagement that demands a more holistic adoption of health literacy approaches, alignment across platforms, and suggests an opportunity for an integrated approach to participant engagement.

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4 Background Resources

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