



Enhancing Patient-centricity with Veeva eConsent

WHY VEEVA eCONSENT?

Increase site efficiencies

- Overcome the burden of paper
- Reduce the number of errors
- Reduce pressure on the call center

Improve participant experience

- Eliminate the need to carry around large paper documents
- Provide access to information
- Share supporting information

Real-time access to data

- Able to answer questions instantly
- No lost paper consents
- Monitors can access consents ahead of time

With a longstanding digital mindset, Celerion is on a journey to implement new clinical research technologies to conduct trials faster and more reliably. They want to get data to clients faster, while making it easier for participants to take part in studies. Celerion recognized early on that electronic Consent (eConsent) would increase efficiency and improve the participant experience. However, previous eConsent solutions had been unable to meet the needs of Phase I studies, which must consent and process large volumes of participants, quickly.

CELERION AT-A-GLANCE

Company size: 1,000+ employees

Headquarters: Lincoln, NE

Featured Solutions:

- Veeva eConsent
- Veeva SiteVault
- Vault Clinical Operations Suite

Veeva eConsent offers Celerion a scalable solution for their fast-paced environment. Easy-to-use editor tools allow Celerion to create pre-approved consent templates that can be quickly adapted for specific study requirements and easily updated as study requirements change. Patients access their consent documents through MyVeeva for Patients, an easy-to-use application where they can view and complete study activities.



eConsent has been a no-brainer for years, we just didn't have a tool that was fast enough to work in a phase 1 environment.

— Staci McDonald, Vice President Global Scientific Clinical Operations, Celerion



THE BURDEN OF PAPER

Managing a paper mountain	Poor participant experience	Laborious monitor experience
<ul style="list-style-type: none"> • Pushing trolleys filled with paper binders • Storing huge volumes of paper documents • Hours spent copying documents 	<ul style="list-style-type: none"> • Carrying around multiple, large paper documents • Documents often lost (or found in the trash can) • Accessing information at a later date 	<ul style="list-style-type: none"> • >50% of time on-site spent checking consent documents • Most errors involve date/time or legibility issues • Number of hours spent hosting monitors

Benefits for Participants

Celerion has received positive feedback from participants. They found it easy to access, review, and sign consents through the MyVeeva for Patients app. The documents were clearly structured, and they didn't need to be carried around for months, unlike the old paper documents.

There were also a few unexpected surprises in the feedback. Celerion had anticipated that eliminating paper documents would benefit participants most. What they learned, however, is that patients place even higher value on other types of information shared within the MyVeeva document library. This included the study schedule and phone numbers for the nurse's line or their study coordinator. However, the number one benefit listed by participants was having the catering menu available in the MyVeeva for Patients app. This highlights how important it is to think about participant experience as a whole, not just the aspects directly linked to study activities.

BENEFITS (PARTICIPANT RANKING)

1	Access to the study menu	Despite not being part of formal study documentation, seeing the catering menu ahead of time is important to participants, particularly for extended stays at the research facility.
2	Access to the study schedule	Phase I schedules involve multiple appointments throughout each visit so it is important participants' know where they need to be, and when. Previously this was a large paper document, now it's all loaded straight into the MyVeeva app.
3	Eliminated paper documents	Consent documents are typically 10-30 printed pages that need to be retained during the course of a study (and beyond). Moving to an electronic consent solution now means completed consent forms are available on the participant's mobile device whenever needed.
4	Access to phone numbers	~25% of calls to the global call center were simple requests for phone numbers. The introduction of Veeva eConsent, has significantly decreased calls as the information is available in the MyVeeva app and easy to find whenever participants need it.



*It was the easiest thing I did all day!
I love no packet of paper to carry around with me for months.
All of my consents are on my phone and easy to access.*

– Study Participants

Benefits for Celerion Teams

Printing and copying were eliminated almost overnight. Paper consent processes generate huge volumes of paper, resulting in rooms full of documents and trolleys to wheel them from person to person. If a consent form was misplaced, considerable time was wasted searching until the documents were found. Moving to Veeva eConsent changed all that, as documents are automatically filed in the system and instantly available whenever required.

Removing the need to print thousands of pages of blank ICFs (informed consent forms) simplified screening preparation. Not only has this saved time, staff also reported how quiet the room is without a copy machine constantly going, which means they can hear participants better.

The ability to review data has been a real game-changer for Celerion. Documents are available at the touch of a button. This means consents can be conducted in the morning and reviewed by the monitor in the afternoon if required. Plus, if a monitor has a question, staff can look up the answer at home, whereas previously they would have to wait until the next day to go to the data room and check the relevant documents.

Screening logs have also become much more efficient. Previously, paper logs were completed manually during screening and were prone to errors, especially dates and consent version numbers. Using Veeva eConsent, combined with SiteVault, the system automatically completes the subject number, consent signature date, and version number. Monitors can view the information in real-time through a screening log report, with new groups appended to the report as they are added.

BENEFITS



Simplified process to prepare for screening



Real-time review by any staff member



Optimized screening logs



*Paper must be shuttled around from room to room.
We didn't realize how much efficiency we could gain by removing these steps.*

— Staci McDonald, Vice President Global Scientific Clinical Operations, Celerion

Benefits for Monitors

Monitoring efficiency significantly increased with eConsent. Signature dates and times are always legible, and 'overwrites' have been eliminated. Additionally, a report displays the list of participants and their consent version number, which was previously challenging to track, especially when there are many different consent versions.

Most importantly, the number of days monitors spend on-site has reduced as consent forms can be reviewed ahead of time. This means only two hours may be required to check critical documents, instead of the previous eight, which benefits monitors and their host coordinators.

IMPRESSIVE VOLUMES AFTER ONE YEAR



The biggest benefit for monitors and for us is that onsite monitoring is 100% not necessary for eConsents.

— Staci McDonald, Vice President Global Scientific Clinical Operations, Celerion

Overall outcome

The introduction of eConsent has increased efficiencies across the consenting process. Perhaps even more importantly, it has been well received by study teams, sites, monitors, and participants.

Celerion report the biggest benefits are as follows:

- ➔ Monitoring time efficiencies have increased as consent documents can be reviewed ahead of time. Many queries that would have previously arisen from basic errors or legibility issues have been eliminated altogether.
- ➔ Calls to the Recruitment Call Center have reduced significantly as simple questions regarding schedules and phone numbers can now be easily found in the MyVeeva app.
- ➔ Electronic consents are automatically filed and can be accessed at any time. This has removed the infrequent, but resource-intensive searches that occurred if a consent document was misplaced.
- ➔ Communication with participants is more efficient. Participants can be kept up to date with schedule changes more easily, and the ability to share any document has significantly improved the experience of participating in clinical research.

BIGGEST IMPACT FOR CELERION



**Efficiency of monitoring
time on site**



**Decrease in phone calls
from participants in
recruitment call center**



**No lost
paper consents**



**Sharing documents
with participants
throughout the study**



The continuity of having information at your fingertips and being able to answer questions instantly is invaluable.

— Staci McDonald, Vice President Global Scientific Clinical Operations, Celerion