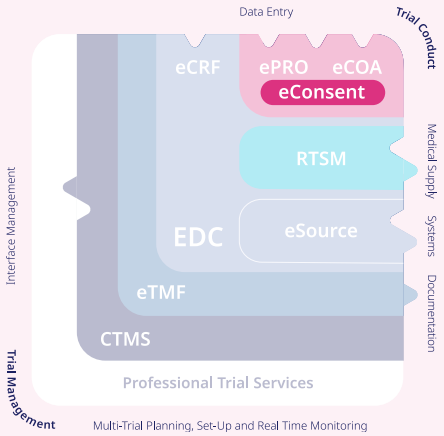
# oomnia eCONSENT




## ENHANCING SPEED AND EFFICIENCY WITH OOMNIA eCONSENT

**Effortlessly obtain participant consents with oomnia eConsent**

oomnia eConsent presents informed consent documents in the participant's chosen language, significantly enhancing understanding and compliance. The built-in Q&A module allows participants to directly communicate with site staff, fostering a supportive environment. The digital signing process reduces the time needed to disseminate consent information to just three minutes. Once the participant's consent is signed, the data is immediately visible within the eConsent system.

- ✓ Seamless eCRF and EDC integration
- ✓ Hybrid electronic and paper consent
- ✓ Interactive multimedia content
- ✓ Web-based BYOD model

## KEY FEATURES OF OOMNIA eCONSENT

**Streamlining clinical trials with unmatched efficiency and compliance**

### SEAMLESS EDC INTEGRATION

oomnia eConsent is fundamentally integrated into our oomnia ecosystem, resulting in a streamlined process. If using other systems, our experts can integrate our eConsent with any external EDC or CTMS, ensuring that it aligns perfectly with current workflows and data systems.

### COMPLIANCE AND SECURITY

Our system is built to comply with international regulatory standards, including GDPR and HIPAA, ensuring that all participant data is handled with the utmost security. Regular audits, end-to-end encryption, and strict access controls guarantee data integrity and privacy.

### CONVENIENT USER EXPERIENCE

An intuitive interface ensures that participants can easily navigate the consent process without confusion or delays. The focus on user-friendly design enhances participant engagement and significantly reduces the likelihood of errors and misunderstandings.

### INTERACTIVE CONTENT

Our system is built to present multimedia content as well as Q & A sections to participants. Participant questionnaires can also be implemented and tracked, ensuring participant engagement and understanding of the ICF and clinical trial.

### HYBRID CONSENT PROCESS

oomnia eConsent is built for the patient-centric future. Traditional DCTs rely only on eConsent processes, enable patient choice and adapt to their workflows by allowing them to choose paper or electronic consent processes with ease and enable their participation regardless of their technological prowess.

### BYOD MODEL

Our oomnia eConsent is built on a web-based interface that is easily accessible via a smartphone, tablet, or web-browser via a URL. It runs natively on all smartphone, tablet, or computer browsers eliminating the need to special installations, devices, or extensive training for users thus dramatically decreasing costs and overhead.

# ADVANCED FEATURES OF OOMNIA eCONSENT

**Unlock the full potential of your clinical trials**

## TRUE PATIENT-CENTRIC DESIGN

| FEATURES | DESCRIPTION |
|---|---|
| **Hybrid electronic and paper consent** | • Within on study, participants choose the process best suited to their schedule, lifestyle, and background<br>• Simultaneously support, track, and report both electronic and paper-based consent processes |
| **Mobile and web access** | • Intrinsically Bring Your Own Device (BYOD) based<br>• Accessible via smartphone, tablet, or computer |
| **Patient support** | • Integrated Q&A<br>• Multimedia content accessible on any device<br>• Creation of patient questionnaires to ensure understanding of study procedures |
| **Automatic integration with the study database** | • Consent status is automatically integrated with the study database in real time<br>• Integrated graphical reports can be created to track and manage aspect of the consent process |
| **Multilingual support** | • Participants automatically receive eConsent content in their language of choice<br>• Content and ICF language and version are set in the eConsent module or in the participant eCRF itself |

## REAL TIME REPORTING

| FEATURES | DESCRIPTION |
|---|---|
| **Integrated graphical reports** | • Create graphical or tabular reports from any data or meta-data, including audit trials, from or between any EDC documents in the system<br>• Template, name and give Role based permissions to reports |
| **Templated data listings** | • Granularly create and export data captured in any EDC document (data dumps or reports)<br>• Select and template exports by choosing visits, pages, or single fields in any combination, and in any combination of countries, sites, participants and more |

## STREAMLINED PROCESSES

| FEATURES | DESCRIPTION |
|---|---|
| **Native oomnia integration** | • Eliminate manual data transfers and time-intensive and costly reconciliation and verification<br>• Seamless transfer of participant data from the oomnia unified clinical research software to eConsent and vice versa |
| **Real-time notifications** | • Immediate notification for sites staff and participants for required actions or for incomplete processes |
| **Advanced digital signatures** | • Compliant with 21 CFR Part 11, EU Annex 11, and EU Regulation No 910/2014<br>• Any type of ICF is possible, including pediatric studies, including a multiple signature process<br>• Certificate of Completion for signatories upon ICF export<br>• PIs and patients notified of signature execution |

## DATA SECURITY AND PROTECTION

| FEATURES | DESCRIPTION |
|---|---|
| **Encryption, access, and authentication** | • All data is encrypted both in transit and at rest to protect against unauthorized access<br>• Prevent unauthorized access with state of the art user authentication methods<br>• Role based access ensures only authorized personnel can access sensitive data |
| **Data protection regulations conformity** | • Adheres to global data protection laws such as GDPR, Swiss Data Protection Law, and HIPAA |
| **Robust audit trails** | • All actions by all users recorded in an event log<br>• Detailed audit trail for site staff and participants exportable at any time |