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# Electronic Informed Consent (eConsent)

*A Vendor Perspective*

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Patient Solutions

# IQVIA eConsent: The Global Industry Leader

More than 200 studies launched in over 50 countries, across nearly every therapeutic area



**5,000 sites**



**15,000 site users**



**30 pharma clients**



**50,000 patients**



**60 languages**



**14 years**



## Countries

Argentina	Guatemala	Poland
Australia	Hong Kong	Romania
Austria	Hungary	Russia
Belgium	Iceland	Saudi Arabia
Brazil	India	Singapore
Bulgaria	Israel	Slovakia
Cameroon	Italy	South Africa
Canada	Japan	Spain
Chile	Korea	Sweden
China	Latvia	Switzerland
Czech Rep	Malaysia	Taiwan
Denmark	Mexico	Thailand
Egypt	Netherlands	Turkey
Estonia	New Zealand	Ukraine
Finland	Norway	United Kingdom
France	Peru	United States
Germany	Philippines	Vietnam
Greece		

**Extensive experience with both central and local IRBs and Ethics Committees**



## Therapeutic Areas

Bone / Osteoporosis	CNS / Neurology
Hematology	Infectious Diseases
Ophthalmology	Pulmonology
Cardiovascular	Dermatology
Immunology	Endocrinology
Inflammation	Nephrology
Respiratory	Vaccines
Diabetes	Gastroenterology
Internal diseases	Oncology
Rheumatology	Women's Health
Orthopedics	



## Signature Modalities

eSignature - in about a dozen countries  
Print-to-Sign – accepted globally

# eConsent Benefits

# Why Use eConsent?

*Paper consent forms are fraught with problems that cost time and money*



**Difficult language**



**Inconsistent messaging**



**No transparency / accountability**



**No audit controls**



**Frequent regulatory failures**



**Poor version management & control**

# eConsent Benefits Everyone in the Clinical Trial

*Proven value for all stakeholders in the clinical trial process*



## Participants

- View multimedia education & flag question areas
- Better understand risks and benefits
- Higher levels of satisfaction
- Better adhere to protocol



## Trial Staff

- Eliminate repetition in explanations and providing own definitions
- Version and document management
- Automatically record consent notes
- Streamlined re-consents



## Monitors

- View real-time consent status across sites
- Easily access detailed audit trails
- Rely on date/time stamps
- Access optional consent element reporting



## Sponsors

- Assured of the integrity of the consent process
- Fewer consent-related audit findings
- Global signature compliance
- Useful analytics
- Better recruitment and retention rates

# eConsent System Components

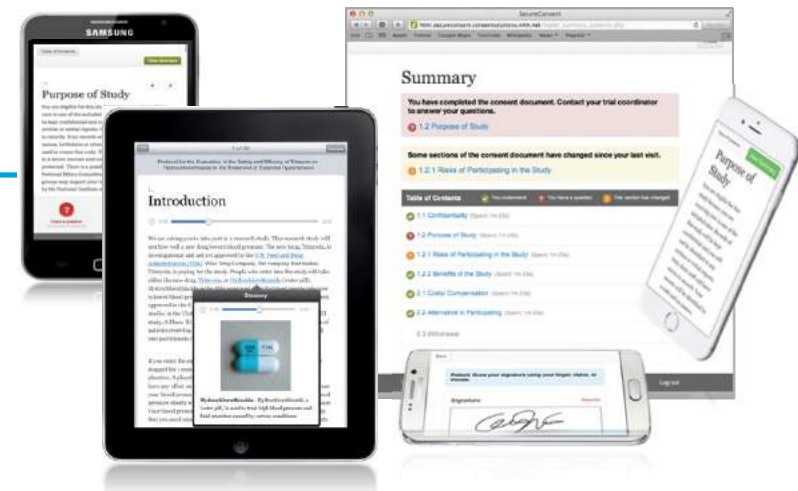
*One web-based system with controlled access for all stakeholders*

**A web portal that can be accessed from a desktop, laptop or any Internet-enabled device at the study URL:**

- N. America & LATAM: <https://iqvia.secureconsent.com>
- EMAE & APAC: <https://iqvia.secureconsent.eu>

**A patient-facing tablet that staff set up for each patient to use on site**

- Devices are not taken home
- Require an Internet connection, as no data is stored on the device
- May use dedicated iPad or deploy on an eCOA / ePRO device
- Patients never need a login or password
- Provides a simple, secure, and mobile way for patients to read at their own pace





# Data Security and Privacy

## ELECTRONIC INFORMED CONSENT *System Overview and Security Features*

SecureConsent is a fully validated electronic informed consent (eConsent) system in use for clinical research in the US since 2005 and in the EU since 2009. It was designed to improve quality, efficiency and transparency for sites and sponsors throughout the clinical trial process, while improving potential participants' comprehension, knowledge retention, and satisfaction compared to a paper-based consent process.

### eConsent Hardware

The eConsent system is device-agnostic and can run on Apple, Android, or Windows based hardware, and the system can be deployed on numerous third-party eCOA devices for patient-facing activities. Monitors, CRAs, Auditors, and Site Staff will be able to engage in ICF preview, reporting, analytics, and other administrative functions from both the mobile device and desktop systems, according to the role-based access. Touchscreen devices are ideal for patient-facing activities as they facilitate biometric advanced electronic signatures and simplify usability. The system runs from redundant HIPAA/PCI certified data centers where dedicated servers are hosted. These servers are Dell PowerEdge R710s running Windows Server 2012 and Microsoft SQL 2012. The tablets running eConsent do not store data locally, as anything that is captured is immediately transmitted to the secured servers over an encrypted connection. Data centers are all equipped with redundant firewalls, which are continually monitored and regularly audited by IT staff.

### Security Features

1. SecureConsent is a validated FDA 21 CFR Part 11 and EC Annex 11 compliant system for electronic informed consent that runs under a controlled quality system.
2. The application and its supporting network infrastructure are regularly subjected to state-of-the-art vulnerability scans and penetration tests executed by a validated independent third party.
3. All data handled by SecureConsent are encrypted in transit and at rest. SecureConsent uses AES-256 encryption over the HTTPS/TLS protocol. No unsecured sessions are permitted under any circumstances. This means that even if the data is hacked or intercepted, it will be indecipherable and meaningless.
4. Study sites use SecureConsent on touchscreen tablets, but no data is ever stored on tablets. Data is immediately encrypted and transmitted to the central server upon capture. There is no risk of inappropriate disclosure should a tablet be lost or stolen.
5. Tablets are configured with AirWatch Mobile Device Management software, which limits the device to be used for its intended purpose, restricts the URLs that can be accessed, and allows the support team to remotely troubleshoot, disable or update the device, or locate it if it is lost.

# Data Security and Privacy

- Data encryption (AES-256 in transit and at rest)
- Private hosting environments (US, France, Germany)
- Fully redundant systems
- Annual disaster recovery tests
- Certified by the US Department of Commerce and by the US-EU Privacy Shield program
- Sensitive information is data-fenced
- All data is stored in tamper-proof and unalterable databases
- Web application and network infrastructure tested by a validated independent third party



# Regulatory Compliance

## ✓ 21 CFR-Part 11 Compliance

- Robust documentation of SDLC, SOPs & Policies
- Extensive, ongoing systems validations
- CAPA program
- Training Programs
  - › GCP
  - › Site-staff training and documentation
- Detailed audit trails
- External/Internal Audit Procedures
- Risk Assessment

## ✓ HIPAA/PCI Compliance

## ✓ Privacy Shield Certification

## ✓ EU Annex 11

## ✓ EU Data Privacy Laws

## ✓ EU eIDAS compliant

- *EU Servers located in Frankfurt and Strasbourg*
- *All PI/PHI stays in EU*
- *Aggregated / De-identified data can be viewed outside of EU*



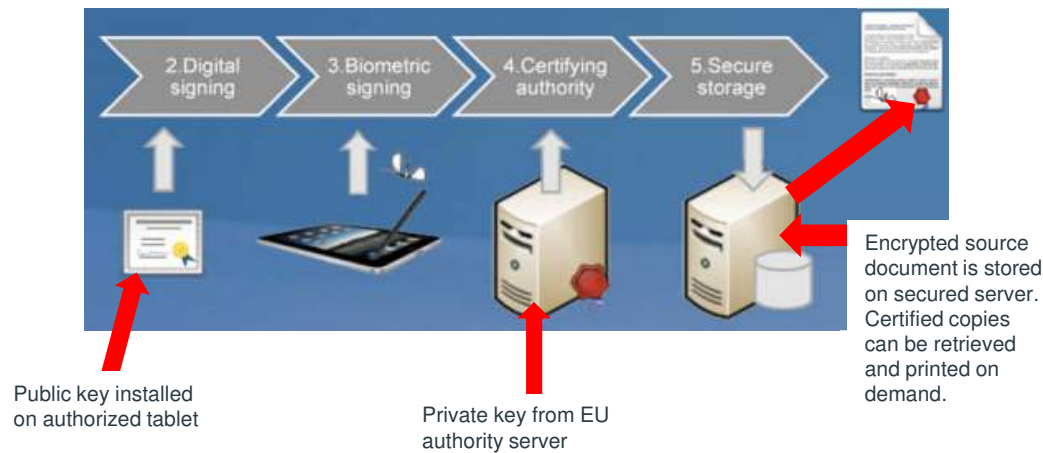
EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH



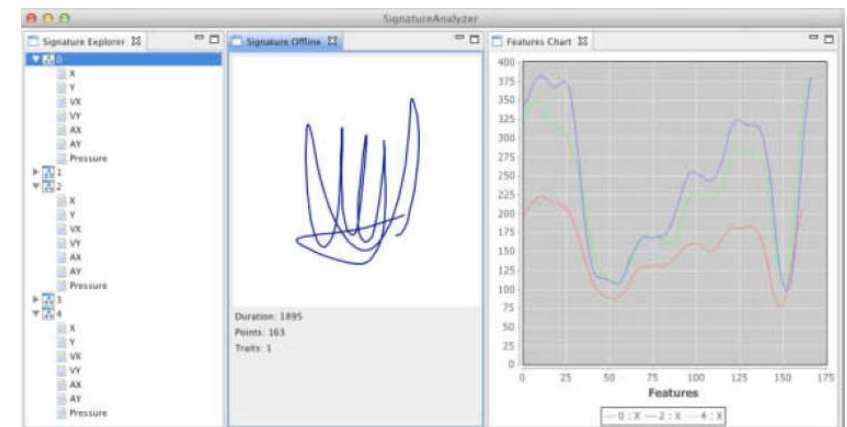
# Biometric Electronic Signature

## ✓EIDAS-Compliant Signature

- EU Advanced Electronic Signature compliant
- Forensically identifiable – superior to wet-ink signature
- Legally binding
- No PKI key required by patient



In case of dispute, the biometric signature can be extracted from the document to provide a forensic examiner with a signature analysis tool to verify the signer's identity.



The legal validity of the signature is achieved in two ways:

1. The identity of the signer can be determined manually by an expert and automatically with very high certainty.
2. The signature is embedded and hashed within the document and cannot be removed except by injunction.

# Demonstration...

## e-Consent

### The consent process:

1. The patient views a short getting started video, then touches "Begin"
2. Patient slides the button to the right for Understanding, left for Questions
3. Questions can be addressed immediately or prior to signature
4. A Summary page shows question areas marked in red
5. Click each question; after clarification, ask the patient to move the slider right
6. Once all sections are understood, the document can be signed

**Risks**

As in most cancer studies, patients participating in this research will be exposed to risks. Possible risks include, but are not limited to, the risks associated with the study drug. The nature of side effects experienced following administration of this study drug may lead to weakness or a variety of other symptoms such as fatigue, pain, and dizziness. You have been informed of the risks of participating in this study. You understand the risks of participating in this study. You are willing to accept the risks of participating in this study. You understand the risks of participating in this study. You are willing to accept the risks of participating in this study.

**Consent**

I have read and understand the risks of participating in this study. I understand the risks of participating in this study. I am willing to accept the risks of participating in this study.

**Consent**

## Add a Patient

### Prepare the tablet for patient consent:

1. Click the green button at top left to "Add a Patient"
2. Select the patient language and click "Add"
3. A blue bar at top confirms the new patient record
4. Click on the "gear" icon to the far right of the patient record
5. Select "Consent Patient"
6. Confirm patient identity and hand the tablet to the patient

**eICF Demonstration Study**

SEARCH & FILTER: Search (Go) | Filter

1 Add a Patient

2 Consent Patient

Processing File	Status	Actions
P110 Shing (Shing) - 10/10/18	Not consented	Change Status
P111 Shing (Shing) - 10/10/18	Not consented	Print to File...
P112 Shing (Shing) - 10/10/18	Consented 10/10/18	Get Subject No.
P113 Shing (Shing) - 10/10/18	Consented 10/10/18	Upload Document
P114 Shing (Shing) - 10/10/18	Consented 10/10/18	
P115 Shing (Shing) - 10/10/18	Consented 10/10/18	
P116 Shing (Shing) - 10/10/18	Consented 10/10/18	

Print/Email

## Electronic Signature

Signatures are collected on the tablet and the system generates a PDF of the signed ICF, stored on secure servers as the source document.

1. Select green box "You are Ready To Sign Consent"
2. Tap the Signature box and have patient sign with a finger or stylus (data is automatically recorded)
3. Patient then types their full name and clicks submit (Be sure spelling is correct!)
4. Scroll down and repeat for each required signature box (Spellcheck Again!)
5. Click Submit Signatures at the bottom of the page
6. If there are no other documents to sign, select Close
7. The system will automatically log you out when completed.

**Summary**

1 You are ready to sign the consent document.

**Next Actions**

- Introduction (1/1)
- Risks (1/1)
- Benefits (1/1)
- Costs (1/1)
- Confidentiality (1/1)

**Patient**

I have read this information and it has been written in a language that I can read and understand. All my questions about the study, possible risks and side effects have been answered to my satisfaction. Based on this information, I volunteer to take part in this study.

How can we reach you? (Optional)

Phone

Date

**Submit Signatures**

# Audit Trail

*The audit trail keeps a reliable, unalterable record of all consent-related activities*

- The audit trail shows all activity taken by or on behalf of the participant:
  - Start of consent visit
  - Document version read by the patient
  - Study staff involved in consent visit
  - Question areas
  - Viewed glossary terms
  - Time to read consent and when all areas were marked as “understood”
  - Note to files
  - Electronically signed documents
- **With print-to-sign, source documents are kept on site and no PII is stored in the system; signed documents can NOT be printed from the portal**

The screenshot displays the DrugDevSpark eConsent interface. At the top, it shows the user 'training@secureconsent.com' and navigation links for Dashboard, Analytics, and Help. The main content area shows a patient ID '014' with a 'Consented' status. Below this, there are four summary cards: '4m 32s' (Time to Consent), '4m 1s' (Expected Time to Consent), '3' (Number of Questions), and '0' (Number of Glossary Terms Viewed). A 'Signed Documents' section on the right shows two documents: 'Main: 5 on 2018-08-01' and 'Substudy: 1.1 on 2018-08-07', each with a 'Print' button.

The audit trail table below shows a list of activities:

Datetime	Action	Description
2018-08-07 13:10 CEST	PHI Access	Substudy: training@secureconsent.com printed certified copy of 014 1.1
2018-08-07 13:10 CEST	PHI Access	Substudy: training@secureconsent.com printed certified copy of 014 1.1
2018-08-07 13:09 CEST	Logged Out	Logged out.
2018-08-07 13:09 CEST	Signed Documents	Substudy: Signed document 1.1, confirmed by training@secureconsent.com
2018-08-07 13:09 CEST	Signature	Substudy: Patient signed the document.
2018-08-07 13:09 CEST	Understood	Substudy: Another (Confirmed understanding despite rushing.) (Spent: 3s)
2018-08-07 13:09 CEST	Viewed	Substudy: Another
2018-08-07 13:09 CEST	Understood	Substudy: Trial Section (Confirmed understanding despite rushing.) (Spent: 8s)
2018-08-07 13:09 CEST	Viewed	Substudy: Trial Section

A context menu is overlaid on the left side of the audit trail table, with a red box highlighting the 'View Details' option. The menu items are: Consent Patient, View Details, Change Status, Note to File..., Set Subject No., View Signatures, Print/Email, and Upload Document.





**Thank you!**

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