Future trends for online EDC in clinical studies:

INTrial© Application on PCs, Tablets and Smartphones
Table of Contents

Executive Summary ................................................................. 3
Introduction ................................................................................. 4
  New ways of online device usage in clinical studies ......................... 4
Possible EDC approaches - a new way of data entry .......................... 5
  What’s on the market ................................................................. 5
Apps versus WebApps .................................................................. 5
INTrial© Solution ........................................................................ 6
  INTrial© uses Web-Approach ....................................................... 6
  INTrial© uses One-Web-Application-Approach .............................. 7
Purpose rules platform .................................................................. 7
Look Inside .................................................................................. 8
Outlook ...................................................................................... 10
Résumé ..................................................................................... 10
About Kantar Health Clinical Research .......................................... 10
About INTrial© ........................................................................... 11
Contact ...................................................................................... 11
Disclaimer .................................................................................. 12
Executive Summary

The positive effect of electronic data capture (EDC) on the increase of data quality and on the decrease of time to generate clean data is well known. Today the question no longer is “Shall we use EDC instead of paper work?” but to gain insight in the advantages and pitfalls of the various solutions available.

IN Trial© is Kantar Health' proprietary EDC platform combining more than 30 years of Clinical Research Organisation (CRO) expertise with professional competence in application service provision. IN Trial© provides a comprehensive suite of frontend and backend solutions integrating:

- Study management features to closely track the administration of pre and post enrolment tasks
- Online data capture with multi-language support
- Data management and monitoring tools for query processing, various ways of data locking and an extended range of validation possibilities
- SAE dialogue with direct communication to pharmacovigilance

While many efforts were invested to optimize EDC solutions on the backend side with respect to the integration of elaborated data management options, only little steps were taken to optimize usability on the user interface side.

Despite the introduction of electronic case report form (eCRF) dynamics and query dialogues, EDC still is almost completely encased in a traditional working environment with a classical keyboard interface and with limited or no possibility to trace patients throughout their course of investigations, diagnostics and assessments.

Wireless Internet connection combined with a new generation of e-mobility solutions like Smartphones and Tablets imply a major change in the EDC paradigm. Within the next few years Tablets will be quite a common occurrence as work tools, just the way Smartphones already are.

Recent enquiries with our long-year clients and partners in clinical trials showed an increasing interest in the mobile aspects and predict that the Tablet concept is promising for clinical studies.

These new devices also affect the way online EDC software has to be built. Different devices require different usability considerations, e.g. smaller screens, handling by finger touch instead of external keyboard or mouse - just to name a few.

This whitepaper shows how
- to migrate the established “Web Application” approach to touch screen devices
- to use an “One Web Application” approach for all possible devices
- to allow cost-effective clinical trials also on touch screen devices
Introduction

Regulatory pressure and intensified competition force “faster time to market”. EDC with web-based systems have proven to significantly reduce development cycles and time to approval compared to classical paper CRF processing.

But where is EDC now? Web-based systems are the current state of the art but still reside in a fragmented environment where source data are kept in different systems in different places.

The reason is the nearly unchanged user situation for entering patient data: still EDC is almost completely encased in a traditional workflow. Data entry is done on local computers after data collection. It is not established nowadays to trace patients and to document patient data directly throughout their course of investigations, diagnostics and assessments. Direct interfaces between EDC systems and medical devices or source data records are not likely in the nearby future.

For compensating these restrictions steps have to be taken to integrate the data entry process into the daily study workflow resulting in better compliance and enhanced data quality.

Therefore, the challenge today is no longer just “paper versus online” but rather to keep up with the rapidly changing technical achievements and possibilities. The inventions have progressed more and more into mobile devices like Tablets or Smartphones. These devices allow a just-in-time use based on the actual workflows and people can choose freely the work equipment which is most fitting for their needs.

New ways of online device usage in clinical studies

The participants in clinical studies are quite diverse and range from big hospitals to doctors with practices or even patients who are involved in data capture. Hence the existing electronic equipment is differing extremely. Nevertheless our experience in international web-based studies shows that even in less technically advanced areas the use of an online web-based study application is the easy, secure and best possible way for capturing electronic data.

Additionally, the almost unrestricted and flexible carry-around possibilities of mobile devices for data capture and data evaluation promise a very viable utilization. The future progress of EDC data capture has to apply to different needs:

- Some data could be captured during a visit or a consultation and directly entered using a Tablet interface. Long texts are not likely to be typed often in clinical studies, so the typing with the virtual Tablet keyboard will be uncomplicated. Dates or numbers can also be entered without problems, and click or select fields can be accessed with the finger similar to a computer mouse.
- For extended data entry or for using archiving-, printing-, monitoring- or exporting-functions a PC interface still is more comfortable to work with.
- Patient report outcome (PRO) data also are integrated actively in studies, they can announce daily data like symptom profiles or fill-in other questionnaires. Patients can easily use their Smartphone to provide these data to their physicians.

Clinical trial-related personnel respond very positively to the mobile device topic which makes the Tablet concept quite promising for clinical studies.
For the first time there are viable Tablets on the market and according to the forecasts Tablets will be widespread within the next one or two years for various business needs. For Smartphones the market penetration has already occurred.

Even the first models of PC-touch-monitors are available now. Therefore, the distinction between classic PCs and Tablets will become blurred in a couple of years anyway, e.g. scrolling or pointing on a PC-monitor can improve user interfaces besides mouse usage.

In the following we will provide you with an overview about possible mobile approaches and you will become familiar with the INTrial© solution for your next EDC projects.

Possible EDC approaches - a new way of data entry

What’s on the market
Although Tablets like iPads are well available by now and Smartphones are widely spread, a lot of established Electronic Data Capture (EDC) systems for clinical studies are not designed for Tablet interfaces. Instead, they seem still restricted to PC data entry.

Already now quite a variety of small tools exist which can be a useful addition for data capture. These, however, do not replace a clinical EDC application; they rather are designed as add-ons usually running on Smartphones in order to handle a specific topic within the field of EDC.

Apps versus WebApps
When providing an EDC solution for the users of Tablets or Smartphones, there are basically two approaches which are also used for classic PCs:

1. Application (App): Locally installed software
2. Web Application (WebApp): Website which is accessed by using a browser

The following table gives an overview on the requirements as well as the pros and cons:

<table>
<thead>
<tr>
<th>Requirement</th>
<th>App</th>
<th>WebApp</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local installation of software and software updates</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Working offline</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Local data storage</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Centralized data storage / data actuality</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Circumstantial manual data synchronization online</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>General platform compatibility</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Necessary user hardware support</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Centralized study application adaptations possible</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Necessary rollout using an application store</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Distinct application versioning (version rollout)</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Required internet connectivity for data capture</td>
<td>No</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Taking all aspects into consideration, the comfort of offline usage can easily lead to major complications like data synchronisation failures or even data loss. The support efforts might also increase with local installation or updates performed by the users themselves. Therefore, a well-founded decision has to be made.
INTrial© Solution

INTrial© is Kantar Health’ proprietary online EDC platform for data entry, data validation and data management in clinical trials and has been successfully used in a great number of national and international studies for over ten years.

So far INTrial© focused on a PC interface for data entering. With regard to the progress of mobile interfaces and touch screen monitors, we decided to expand our application and developed a touch-enabled interface.

**INTrial© migrates the reliable web EDC approach to Tablets and Smartphone devices.**

INTrial© uses Web-Approach

INTrial© does not use the classic App concept for mobile devices and holds on to web-applications. One important reason for this decision is the fact, that internet connection is no longer an issue nowadays. Tablets and Smartphones usually are delivered together with a built-in internet connection and WIFI is common in physician practices as well as in hospitals. If for any reasons WIFI should not be available the data can be entered with a conventional computer and browser having a wired internet connection.

The online web application benefits from advantages like centralised deployment and data storage, platform-independent development and a flexible web-based user interface.

The major benefits ensuring a fast and cost-effective study set-up:

- Technically mature functionalities
- Flexible configuration possibilities
- No functional re-development necessary
- Platform-independent development
- Consequent progress in application development
- Easy and prompt updates / rollouts possible
- Centralised data storage
- Enhanced data safety/security
- Flexible web-based user interface
- Installation-free accessibility
- Validated development and deployment according to regulative requirements

Therefore we enhanced our EDC suite focussing on an integrated all in one web application:

- Development of touch-enabled interfaces for Tablets
- Development of touch-enabled interfaces for Smartphones
- Optimization of the existing web interface for PC
- Improvement of usability
**INTrial© uses One-Web-Application-Approach**

The One-Web-Application-Approach grants the user an easy access: just use the device at hand or which is most suitable for the actual work task, browse to the study website and INTrial© will automatically lead you to the fitting interface.

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**INTrial© provides one concerted online EDC for usage on mixed devices.**

The major advantages in overview:

- One web application covers all devices, therefore there is no need to run different applications for different platforms
- Device operating systems are not an issue
- Providing one application compatible with all types of devices allows the user to freely select which device to use
- Maintenance is reduced compared to a multi-application scenario
- Versioning and Updates are centralized
- Explicit data synchronisation is not necessary and the risk of data loss or versioning conflicts is eliminated
- Time frame for a study setup including Tablets is nearly the same as in PC-only version
- Study setup costs are significantly lower than in a multi-application version and only slightly higher than in PC-only version

**Purpose rules platform**

Regarding the different study concepts and target groups INTrial offers different packages for specific purposes and platforms. For example:

- Patient reported outcomes (PRO), where patient are likely to use their Smartphone to document questionnaires or daily data like symptom profiles. Here, a Smartphone is a capable and compliance promoting device.
- Clinical studies, where the amount and complexity of data requires larger displays. For these cases a Smartphone would not be very sensible but a Tablet or a PC is a suitable device.

Considering the purpose-based approach we established applicable INTrial© packages for specific devices:

<table>
<thead>
<tr>
<th>INTrial© package</th>
<th>Purpose</th>
<th>Recommended devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>INTrial© PRO</td>
<td>Daily reported Patient Report Outcome (PRO)</td>
<td>Smartphone</td>
</tr>
<tr>
<td>INTrial© Touch/PC</td>
<td>Master eCRF and integrated patients assessments</td>
<td>Tablet / PC</td>
</tr>
<tr>
<td>INTrial© PC Classic</td>
<td>Master eCRF</td>
<td>PC</td>
</tr>
</tbody>
</table>
Look Inside
In the following we grant you a peek inside our new INTrial© interfaces.

1. INTrial© Touch
This interface theme is automatically chosen and displayed when INTrial© recognises a Tablet browser.

![INTrial© eCRF layout on Tablets](image)

The typical touch specific data entry is supported by the virtual keyboard and touch sensitive elements:

![Entering content with touch specific data entry functions](image)
2. **INTrial® PC**
When INTrial® recognises a PC browser, this interface theme is automatically chosen and displayed. The theme is based on the former INTrial® interface and has been enhanced regarding usability aspects.

![INTrial® interface on PC monitors](image)

3. **INTrial® PRO**
INTrial® PRO uses a separate interface for an optimized display on Smartphone devices.

![Selection buttons](image)

![Checkbox selection](image)
Outlook
INTrial© has gained experience in the field of Patient Report Outcome (PRO) for several years. The first PRO application has been developed five years ago and was still designed for web interfaces running on a Compaq iPaq. Since that time INTrial© has pursued this way of data capture. The leap to contemporary Smartphone interfaces was both reasonable and inevitable considering the wide diffusion of these devices.

The availability and usage of Tablets is being more and more established worldwide. There are several manufacturers who announced releases of Tablets for this year and more will follow increasing the general Tablet usage rapidly.

By this time we already implemented and tested our interface for Apple iPad and Google Android Tablets and will continue to add further established devices.

Résumé
The new INTrial© generation allows you an up-to-date realization of clinical trials:

- INTrial© is specifically designed for the concurrent use on Tablet interfaces or Smartphones as well as for classical PC usage.
- INTrial© continues the successful approach of a web application for electronic data capture.
- With INTrial© you have the possibility to allow a multiple-device data entry.
- Using INTrial© you benefit from a cost-effective web application.

About Kantar Health Clinical Research
Late-phase clinical trials are increasingly important for assessing effectiveness, utilisation patterns and monitoring drug safety under real life conditions. Accelerated approval plus regulatory pressure on risk management and mitigation strategies makes it all the more important to be well-prepared for the challenges of safeguarding your drug in a world of demanding healthcare stakeholders – now and in the future. Kantar Health Clinical Research specializes in the following areas:

- Clinical trials
- Non-interventional safety and drug surveillance
- Patient reported outcomes
- Health economics and outcomes

Kantar Health’s Clinical Research expertise comprises:

- Over 30 years of CRO experience
- Global clinical networking capabilities
- Provision of broad knowledge regarding local ethical and regulatory requirements in more than 45 countries
- Broad access to physicians and patients in multiple countries by proprietary panels/databases

Kantar Health is a leading provider of data collection services to the medical and healthcare research industry worldwide and has designated expertise in late-phase-research:

- Adherence to risk management requirements
- Establishment of evidence regarding safety issues
- Certification of data and information security
• Assessment of health outcomes in various settings
• Kantar Health / All global physician panels
• Providing e-Clinical solutions covering the entire project life cycle and providing comprehensive metrics for study progress

About INTrial©
INTrial© is the approved system for online data entry, data validation and data management for clinical trials and benefits from Kantar Health’ long-time experience in the field of online EDC systems. Besides the strong focus on usability and flexibility INTrial© also fulfills all criteria of the FDA CFR Part 11 regulatory demands. INTrial is hosted on our own dedicated servers in our company’s certified data centre.

Feature overview:
• Complex study design realization and efficient creation of eCRFs
• Multi-language support also for non-latin character sets
• Versioning and amendment support for parallel usage of different versions
• User/rights management with fine-grained setting options
• Hybrid versions (eCRF and pCRF) including administration of pCRF workflow
• Double data entry support and paper query processing
• Full data entry validation supporting an extended set of data verification
• Study workflow tools like digital signature, randomization, arm management
• SAE management and reporting with direct communication to pharmacovigilance
• Viewable and reportable audit trails and detailed task logging for documented data consistence
• Monitoring tools for query handling, data locking and user supervision
• Extended reporting, exporting and printing functions

Contact
Are you interested in INTrials© touch screen solution? Do not hesitate to contact us:

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