

A lifetime of care

GET DIGITAL GET **FIT** FASTER INTELLIGENT TRIALS

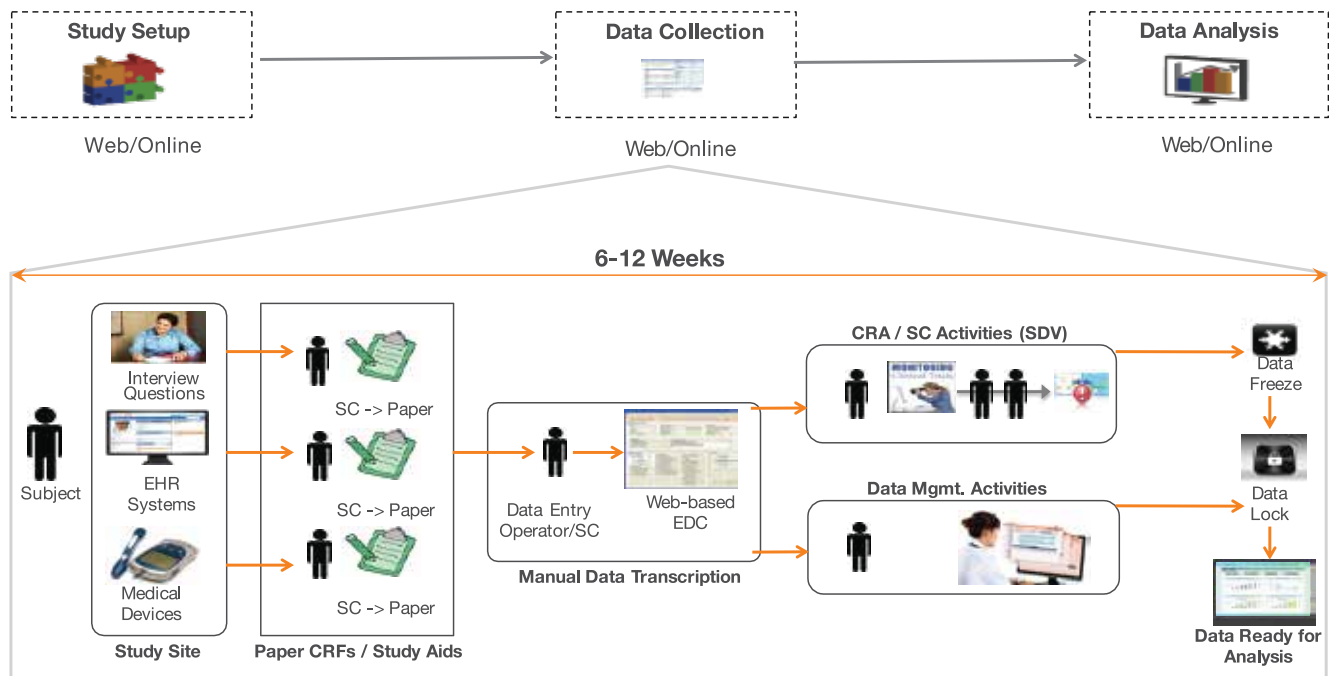
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**eSOURCE DIRECT DATA CAPTURE
AND EDC INTEGRATION**

eSOURCE - THE CURRENT PICTURE

eSource (Electronic source) data are original patient data that are pulled digitally without having to record the data on a piece of paper first, and then transcribe it to an electronic data capture (EDC) system [1]. FDA wants to see direct use of eSource in clinical research in regulatory submissions and has published eSource Guidance in Sep 2013 followed by FR notice in June 2015.

Current practices of clinical data collection are not efficient and involves Site Coordinator (SC) capture interview questions on paper and/or transcribing data from e.g. EHR or from devices via paper route to EDC (SWIVEL CHAIR effect). The whole process is error-prone and hinders real-time analytics as access to clinical trial data by biostatistics & programming is often delayed by 6-12 weeks from the time of original collection at site.



Challenges attributing or resulting from current process, but not limited to, are:

- ☑ Duplication of Data Collection
- ☑ Unreliable internet access
- ☑ Differing metadata and data entry guidelines/requirements in EHR and EDC
- ☑ Inefficient use of EHR to identify eligible patients
- ☑ Delay in data transcription, related quality issues and extensive discrepancy management
- ☑ Significant time spent on SDV (on average 50% of monitor time)
- ☑ Lack of real-time data availability hinders effective decision making and restricts adoption of adaptive trial design

We need

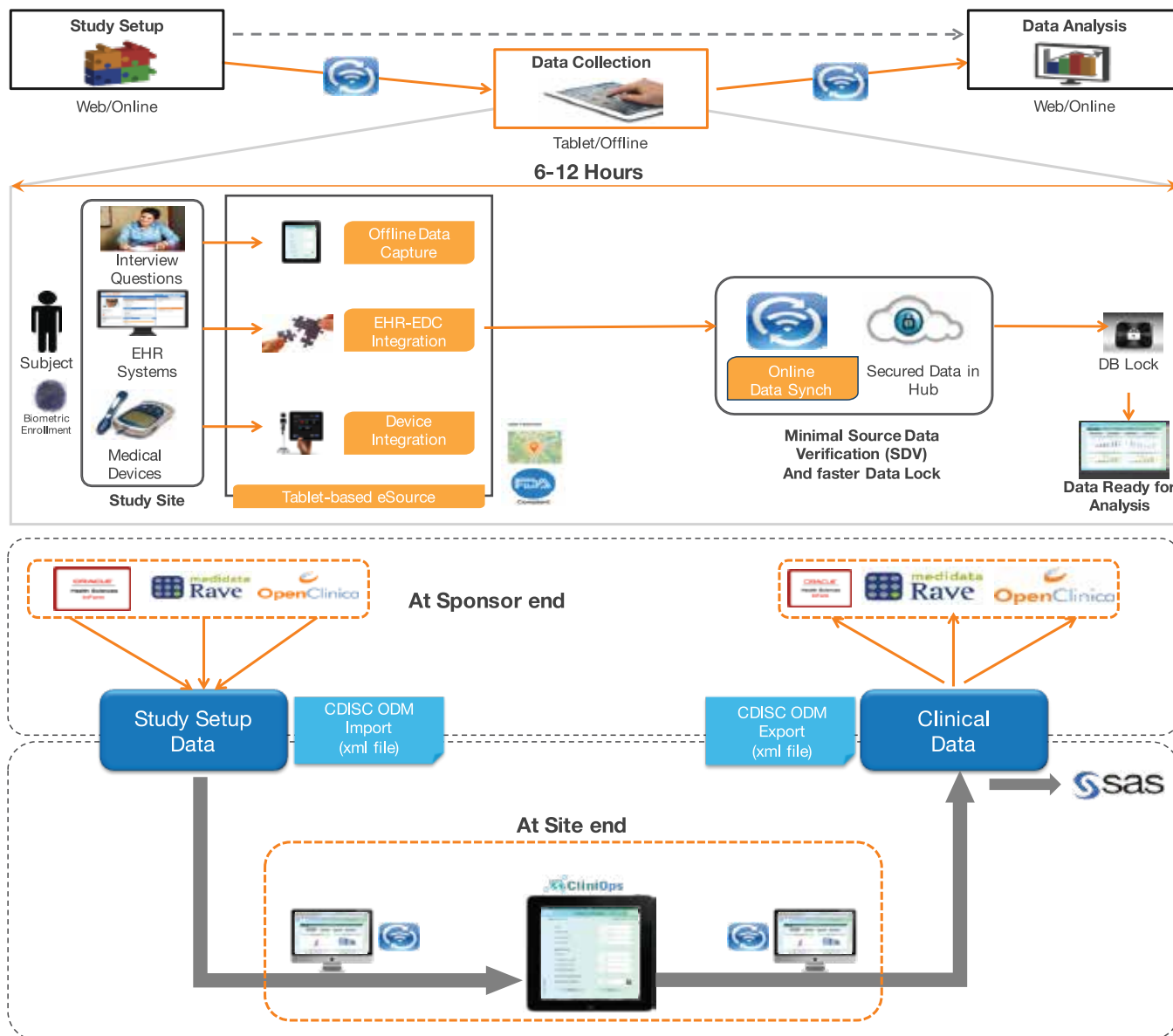
- ☑ Mobility (tablet) based direct data capture solution
- ☑ Offline connectivity and sync-up with backend EDC
- ☑ EHR-EDC integration for automatically transfer relevant patient data into EDC/CDMS
- ☑ Device integration for automatically transfer relevant biometric readings to EDC/CDMS
- ☑ Monitoring Metrics & Trend Analysis

Opportunity

Direct data capture solution will improve overall efficiency in data collection and provides near real-time study status and analytics. It could reduce study time by up to 30%. It will support efficient use of monitor time during site monitoring with reduced SDV and more time for quality interaction with investigators and site coordinators.

HCL eSOURCE DIRECT CAPTURE SOLUTION

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Key features:

- ✓ Offline connectivity and sync-up with backend Clinical systems (built-in Rave adapter)
- ✓ Digital informed consent
- ✓ Easier study set-up and data collection
- ✓ Standards driven integration; supports CCD, FHIR, HL7, CDISC CDASH, ODM
- ✓ Integrated Dataflow, with up & downstream clinical applications
- ✓ Eliminate unnecessary duplication of data and reduce the possibility of transcription errors
- ✓ Minimize duplication of effort and promote use of common data elements from EHR to EDC
- ✓ User Experience - User experience close to native mobile apps (Look & feel, performance, etc.). Availability of Offline access, Device features, Notification, etc.

Benefits

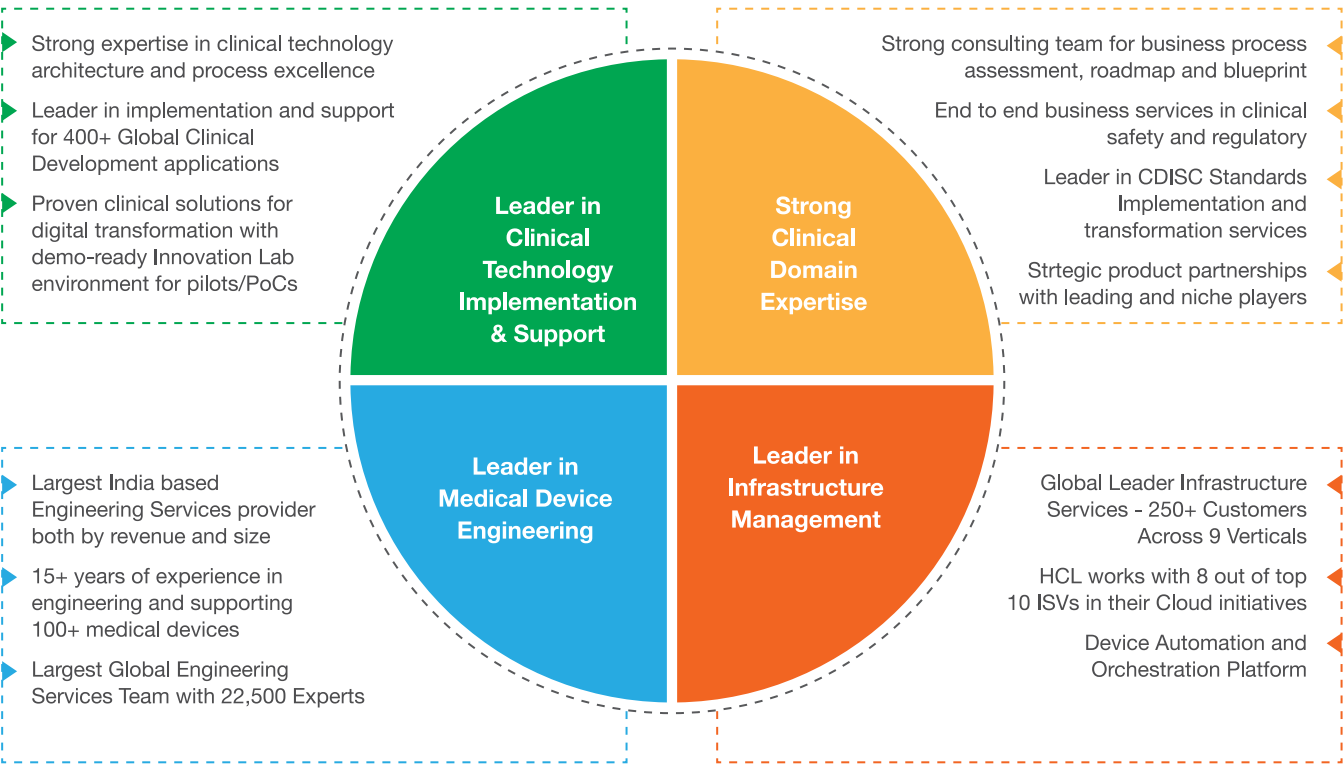
- ✓ **Clinical Trial Sponsor Benefits** - Reduce study time by up to 30%; Reduce data queries by up to 80%; Near-real time study status and analytics
- ✓ **Clinical Trial Site Benefits** - Eliminate paper source, with offline eSource data collection; Mobility in data collection & digital informed consent; Eliminate data transcription; Patient engagement: Alerts & messaging via smartphone
- ✓ **Potential Overall Benefits** - Make it easier for physicians to conduct clinical research; Collect data only once in an industry standard format for multiple downstream uses; Eliminate unnecessary duplication of data and reduce the possibility of transcription errors; and Improve data quality and patient safety

Key Considerations

- ✓ Offline connectivity support
- ✓ User friendly UI for data collection replicating paper based process
- ✓ Improve efficiency and flexibility for site coordinators during data collection
- ✓ Cross platform support - Can be extended to support all mobile platforms easily. Provides native plug-in availability for specific requirements
- ✓ Computer Systems Validation, 21CFR Part 11
- ✓ Patient Data Safety & Privacy
- ✓ Security, Audit & Archival Policies

WHY HCL FOR ESOURCE DIRECT DATA CAPTURE

HCL is a “Full Services Provider” that is uniquely positioned to deliver truly Integrated clinical solutions for pharma. Some of the reasons for HCL’s strong position are as below.



REFERENCE

1. Mitchel J.T., Helfgott J., “eSource Records in Clinical Research”, 2015.

HCL LIFE SCIENCES & HEALTHCARE

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Let's connect:



Please feel free to write to us at contact.lsh@hcl.com

ABOUT HCL

ABOUT HCL TECHNOLOGIES

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