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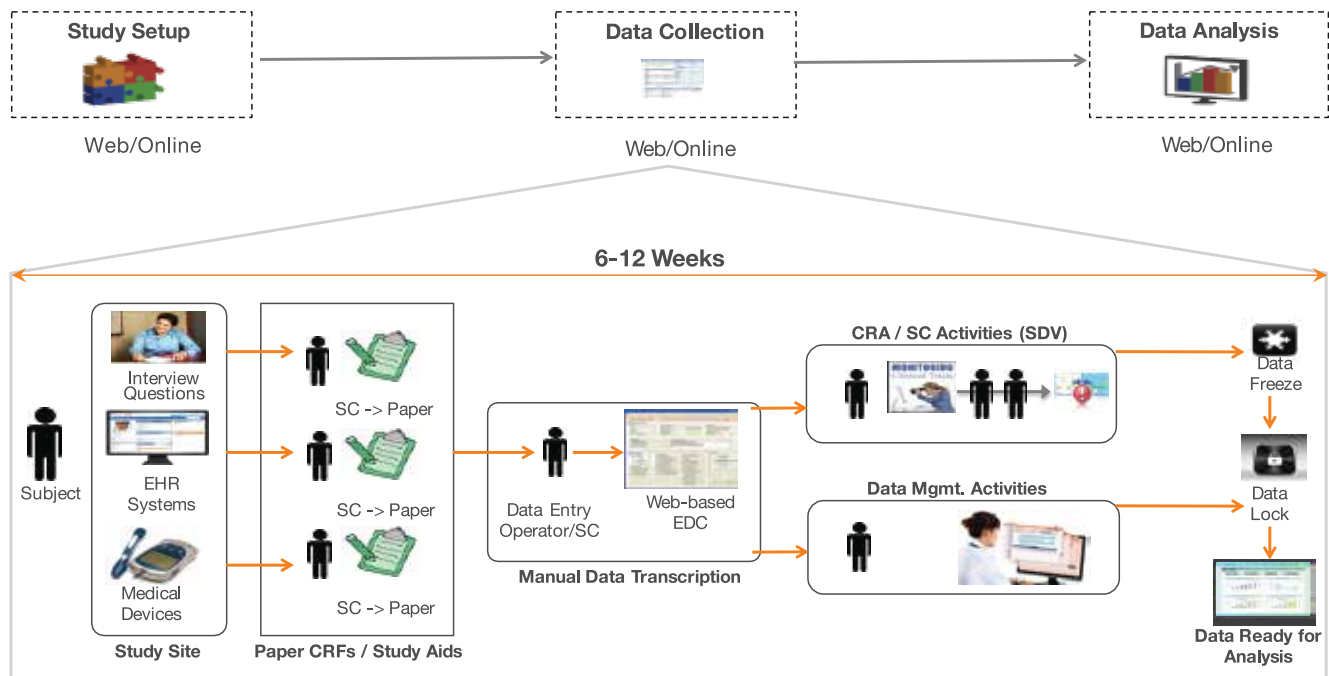
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**eSOURCE DIRECT DATA CAPTURE  
AND EDC INTEGRATION**

## 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**

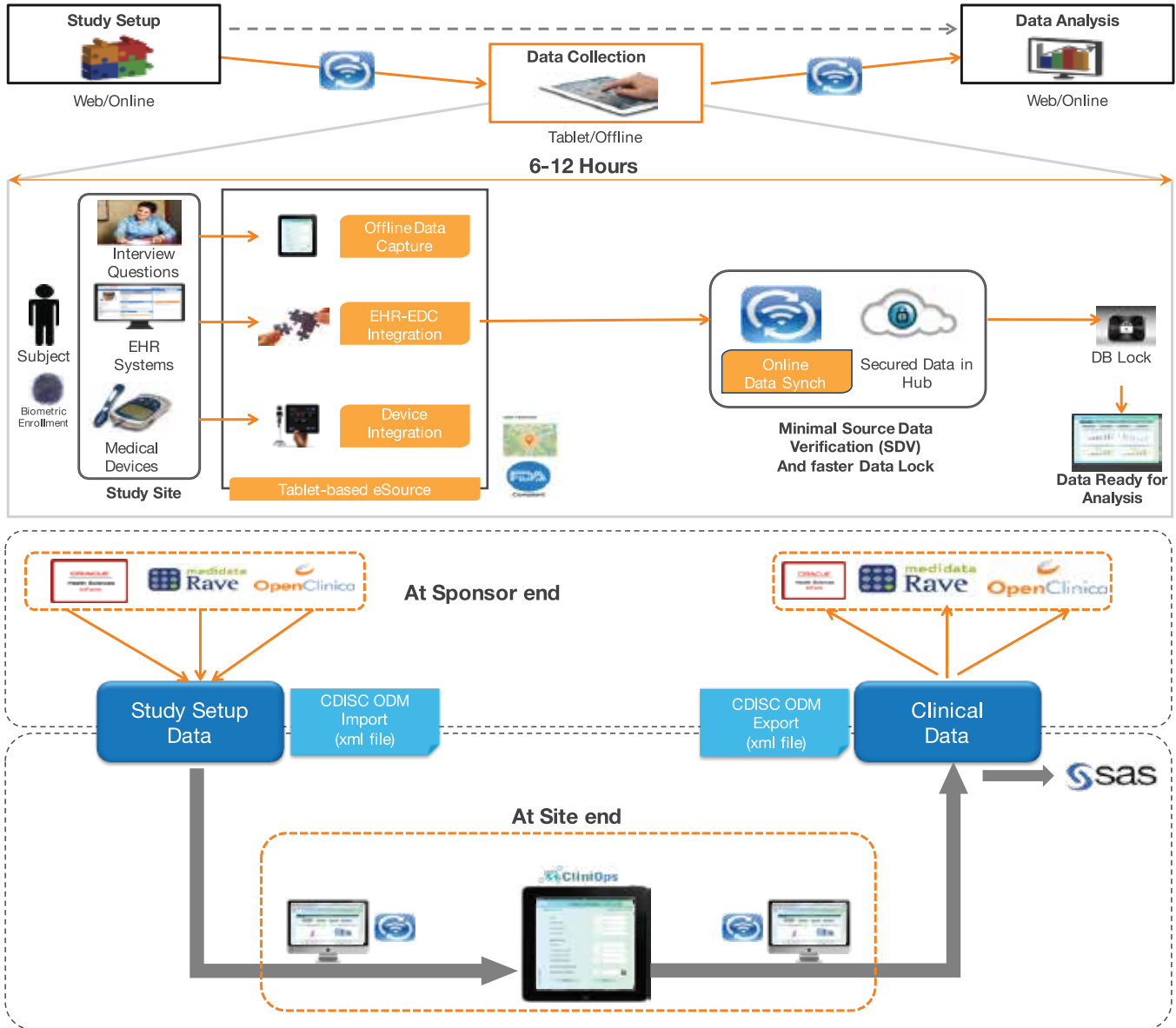
- ☑ Mobility (tablet) based direct data capture solution
- ☑ Offline connectivity and sync-up with backend EDC
- ☑ EHR-EDC integration for automatically transfer relevant patient data into EDC/CDMS
- ☑ Device integration for automatically transfer relevant biometric readings to EDC/CDMS
- ☑ Monitoring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

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.



### 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

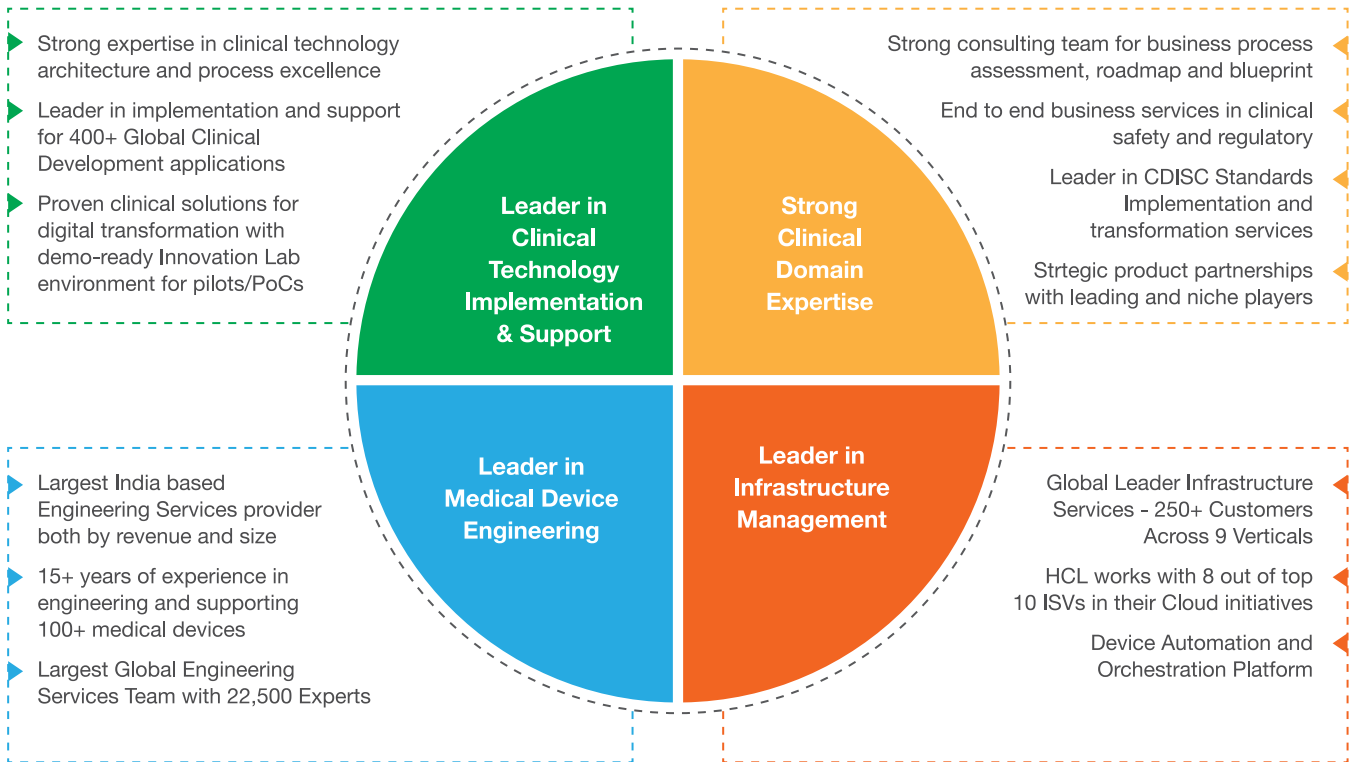
- ✓ **Clinical Trial Sponsor Benefits** - Reduce study time by up to 30%; Reduce data queries by up to 80%; Near-real time study status and analytics
- ✓ **Clinical Trial Site Benefits** - Eliminate paper source, with offline eSource data collection; Mobility in data collection & digital informed consent; 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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HCL is a leading provider of Life Sciences and Healthcare Business and Technology services. We are the chosen service provider for enabling new growth drivers for our clients, providing them with industry leading best practices, taking care of their compliance needs and ensuring gold standard process cycle times. Our clientele includes eight of the top ten global pharmaceutical companies, nine of the top ten medical devices companies, six of the top ten health plans, three of the top five CRO's and two of the top three data providers. Equipped with certified technology experts and domain specialists, HCL offers services in critical areas of the life sciences and healthcare eco system such as drug discovery, clinical development, drug safety, regulatory compliance, manufacturing and plant automation, commercial, Healthcare analytics, Population Health Management [PHM], mHealth, member experience management [MEM], fraud, waste and abuse management [FWA].

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# ABOUT HCL

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## ABOUT HCL TECHNOLOGIES

HCL Technologies is a leading global IT services company working with clients in the areas that impact and redefine the core of their businesses. Since its emergence on the global landscape, and after its IPO in 1999, HCL has focused on ‘transformational outsourcing’, underlined by innovation and value creation, offering an integrated portfolio of services including software-led IT solutions, remote infrastructure management, engineering and R&D services and business services. HCL leverages its extensive global offshore infrastructure and network of offices in 31 countries to provide holistic, multi-service delivery in key industry verticals including Financial Services, Manufacturing, Consumer Services, Public Services and Life Sciences & Healthcare. HCL takes pride in its philosophy of ‘Employees First, Customers Second’ which empowers its 104,000+ employees to create real value for customers. HCL Technologies, along with its subsidiaries, had consolidated revenues of \$6.2 billion in FY 15 as on 31st March, 2016.

For more information, please visit [www.hcltech.com](http://www.hcltech.com)

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HCL is a \$7 billion leading global technology and IT enterprise comprising two companies listed in India – HCL Technologies and HCL Infosystems. Founded in 1976, HCL is one of India’s original IT garage start-ups. A pioneer of modern computing, HCL is a global transformational enterprise today. Its range of offerings includes product engineering, custom & package applications, BPO, IT infrastructure services, IT hardware, systems integration, and distribution of information and communications technology (ICT) products across a wide range of focused industry verticals. The HCL team consists of over 110,000 professionals of diverse nationalities, who operate from 31 countries including over 500 points of presence in India. HCL has partnerships with several leading global 1000 firms, including leading IT and technology firms.

For more information, please visit [www.hcl.com](http://www.hcl.com)



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