CLINICAL DATA CAPTURE AND MANAGEMENT EVALUATION CHECKLIST

This evaluation checklist is designed to act as a guideline for your consideration of the Oracle Health Sciences InForm clinical data capture and management cloud platform in comparison with other systems. While not exhaustive, it does provide a comprehensive set of features and capabilities to consider when determining which data capture and management solution is best suited to your needs – especially as the industry continues to adapt to rapidly evolving business requirements.

The checklist on the following pages is broken down into six categories:

1. *Product Platform*
2. *Process Efficiencies*
3. *Industry Standards*
4. *Integrations*
5. *Performance, Scalability, and Security*
6. *Company / Business / Pricing Processes*

1. PRODUCT PLATFORM

Feature/Functionality	Oracle Health Sciences InForm	EDC System "B"	EDC System "C"
Collaborative, online study design environment for non-programmers with rule development "wizard"	✓		
Comprehensive edit check development and testing capabilities	✓		
CDASH forms library	✓		
Advanced query management with online edit checks and queries	✓		
Targeted SDV down to the item level	✓		
Comprehensive multi-trial medical coding and dictionary support for Con Meds and S/AEs	✓		
Patient randomization, trial supply management, and drug reconciliation	✓		
Lab normals management	✓		
User management and training	✓		
Site provisioning	✓		
Support for late-phase studies	✓		
Device-independent ePRO /eCOA	✓		
Collection and management of genomic data	✓		
Clinical analytics	✓		
Operational analytics	✓		
Medication adherence compliance tracking	✓		
Automated cleaning and transforming of data from 3rd-party data sources to SDTM, SDTM+, ADaM	✓		
Medical image management and adjudication	✓		
Configurable, automated site payments	✓		
Mobility: Support for iOS and Android tablets	✓		
Multi-language and multi-regional functionality in a single environment	✓		
Automatically generate purpose-specific (archival/submission), fully compliant PDF output of clinical content	✓		
Provide wide range of options for PDF content and layout of both blank forms and clinical data forms	✓		
Scalable architecture supports ability to produce submissions content with millions of data points	✓		
eTMF integration or support	✓		
Site document exchange	✓		
Standard dashboard-style reports e.g. queries, data entry, subject enrollment, audit trail, aging and cycle times	✓		
Simple, non-technical ad hoc reporting	✓		
Cross-study analysis on consolidated and standardized trial data	✓		
Automated transfer of S/AE data to safety systems	✓		

2. Process Efficiencies

Feature/Functionality	Oracle Health Sciences InForm	EDC System "B"	EDC System "C"
Integrated systems and workflows	✓		
Single sign-on	✓		
Design studies in as little as 3 days	✓		
Cycle-time from design through UAT and go-live as little as 20 days	✓		
One-click, self-service deployment including mid-study changes	✓		
Built-in study design task workflows	✓		
Define reusable SDTM mappings	✓		
Leverage SDTM data for analysis as well as submission	✓		
Check SDTM data for compliance with the standard	✓		
Sophisticated library search and study object reuse for study design	✓		
Ability to code medical terms within the application and consistently across multiple trials in a single environment	✓		
Allows mid-trial dictionary upgrades with full impact analysis capabilities and support	✓		
Real-time, actionable visibility to trial data across visits and sites, whether an internal or outsourced trial	✓		
Review / manage clinical data across subjects and visits without navigating to each form	✓		
Assess and apply lock status to subjects, sites, or an entire study from a single view in minutes	✓		
Filter real-time data views by site, subject, visit, and data status	✓		
Easily identify data that is new or updated since a previous review	✓		
Automation of configurable workflows with custom review states to target review activities	✓		
Intuitive and efficient user interface e.g. dynamic forms and visits are highly visible	✓		
Move rapidly and easily from site level down to the patient level view	✓		
Raise queries without having to navigate away or toggle between separate windows	✓		
View data across forms in a single view—e.g. Adverse Events and Concomitant Medications— eliminating the need to run separate reports	✓		
One location for designing, deploying, versioning and maintaining changes to a trial	✓		
In-place revisions to design and deploy revisions to an existing study version	✓		
No migration of trial data required for mid-study change e.g. protocol amendment or updated study requirement	✓		
Reports available immediately upon study go-live	✓		
Reporting does not impact transaction performance at sponsor, CRO, or site locations	✓		
Implementation of reusable processes (workflows, transformations, validation checks, forms libraries)	✓		
Support for adaptive trials	✓		
Support for risk-based monitoring following TransCelerate, FDA, EMA, or customer best practices	✓		
Subject and visit status icons viewed with one click	✓		
Comprehensive user management and training	✓		
Trained network of >100,000 sites worldwide	✓		
Independent verification of site preference for EDC system	✓		
Customizable, annotated study book with complete form-by-form representation of the study, T&E schedule, coding and extract maps, reporting structures and more	✓		

3. INDUSTRY STANDARDS

Feature/Functionality	Oracle Health Sciences InForm	EDC System "B"	EDC System "C"
CDISC ODM certified	✓		
ODM data import API	✓		
ODM-based clinical data exchange with external applications	✓		
ODM-based clinical study design metadata exchange	✓		
CDISC Registered Solutions Provider:	✓		
• ADaM	✓		
• CDASH	✓		
• Define-XML	✓		
• ODM	✓		
• Study/Trial Design Model	✓		
• LAB	✓		
• SDTM	✓		
Active member of industry standards organizations and initiatives:	✓		
• CDISC Advisory Council	✓		
• European CDISC Coordination Committee (E3C)	✓		
• CDISC technical teams e.g. Define-XML and Protocol Representation	✓		
• HL7 and HL7 working groups	✓		
• TransCelerate	✓		
• eClinical Forum	✓		
• Tufts Center for the Study of Drug Development	✓		
• OASIS	✓		

4. INTEGRATIONS

Feature/Functionality	Oracle Health Sciences InForm	EDC System "B"	EDC System "C"
Medical coding	✓		
User management and training	✓		
Lab normals management	✓		
Regulatory submissions	✓		
RTSM	✓		
Safety	✓		
Clinical data warehouse	✓		
Analytics	✓		
Medication adherence tracking	✓		
ePRO / eCOA	✓		
Cohort exploration	✓		
Omics data	✓		
Site payments	✓		
eTMF	✓		

5. PERFORMANCE, SCALABILITY, AND SECURITY

Criteria	Oracle Health Sciences InForm	EDC System "B"	EDC System "C"
Comprehensive and frequently updated security, governance, and process controls in place, including for third-party vendors	✓		
Company follows latest in security best practices	✓		
Choice of cloud-based, on-premise, or hybrid delivery model	✓		
System built on open standards	✓		
Proven track record for managing "big data"	✓		
Trial data stored on company-owned and managed cloud rather than a 3rd-party cloud e.g. Amazon Web Services	✓		
Not reliant on a single hosting facility	✓		
Support organization consists of company employees	✓		
Ability to locate trials and their databases on different servers and in different domains	✓		
Ability to use a separate application and database environment for each trial	✓		

6. COMPANY / BUSINESS / PRICING PROCESSES

Criteria	Oracle Health Sciences InForm	EDC System "B"	EDC System "C"
Stable, profitable, established company	✓		
Company has global reach and scale	✓		
Strong, sustained investment in life sciences research & development	✓		
Track record of life sciences innovation	✓		
3rd-party validation of market leadership across eClinical	✓		
Thousands of full-time professionals dedicated solely to life sciences	✓		
Comprehensive in-house audit and compliance and regulatory experience and expertise	✓		
Active participant in ICH, FDA, EMA, MHRA, and PMDA initiatives and discussions	✓		
Track record of successfully conducting thousands of trials across all phases, from simple to complex	✓		
Experience building and conducting trials in >50 therapeutic areas	✓		
Extensive capabilities supporting convergence of life sciences and healthcare business needs	✓		
Company develops and provides a comprehensive end-to-end clinical R&D cloud platform:	✓		
• Activity-based trial planning and budgeting	✓		
• Protocol validation (study/site feasibility)	✓		
• Patient recruitment	✓		
• RTSM	✓		
• Trial management (CTMS)	✓		
• Clinical monitoring	✓		
• Data capture (EDC)	✓		
• Data management (CDM)	✓		
• Analytics	✓		
• Clinical data warehousing	✓		
• Safety	✓		
• Signal Detection	✓		
• Translational research	✓		
System installed and used by all leading CROs worldwide	✓		
Solution pricing competitive with rest of market	✓		
Clear, consistent and transparent pricing	✓		
Flexible pricing – single-study or multiple-study options	✓		
Affordable study-based pricing	✓		
Multi-study pricing discounts	✓		
No additional fee charged for all sites per month from study start through post-study, regardless of whether a site is active	✓		
No vendor Project Manager required for every study for the life of that study for an additional fee, regardless of who builds the trial	✓		
Global team of life sciences professionals with extensive experience designing, deploying, and managing trials	✓		
24/7/365 global help desk support	✓		
Support provided by company employees rather than outsourced workers	✓		
Support available in 6 languages (English, Japanese, French, German, Spanish, and Italian)	✓		

Why Oracle Health Sciences

Backed by the resources of a Global 500 company, Oracle Health Sciences delivers advanced transformative value for clinical R&D in a modular, integrated and scalable cloud environment. We enable you to:

- **Optimize operations** with technology that helps you maximize efficiency across your clinical life cycle
- **Gain actionable insights** from aggregated clinical and healthcare data
- **Innovate** by incorporating genomics, biomarkers and real-world patient data
- **Future-proof** your business with a significant and ongoing commitment to research and development that evolves and grows with you and the industry

With thousands of professionals in offices throughout North America, EMEA, and Asia, Oracle Health Sciences offers unmatched resources to enable your organization's goals today and in the future.

Contact Us

For more information about Oracle Health Sciences solutions visit oracle.com, e-mail healthsciences_ww_grp@oracle.com, or call +1.800.633.0643 to speak to an Oracle Health Sciences representative.

Oracle is committed to developing practices and products that help protect the environment

Hardware and Software, Engineered to Work Together

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