

Welcome to Arable Corporation

Capabilities Presentation



Agenda

- Introductions
- Overview of Arable Corporation
- Arable Perform EDC and CTMS
- Overview of CRO Services
- Overview of Global Submit for Submission Management
- Overview of Data Achieving, Digitization and e Governance

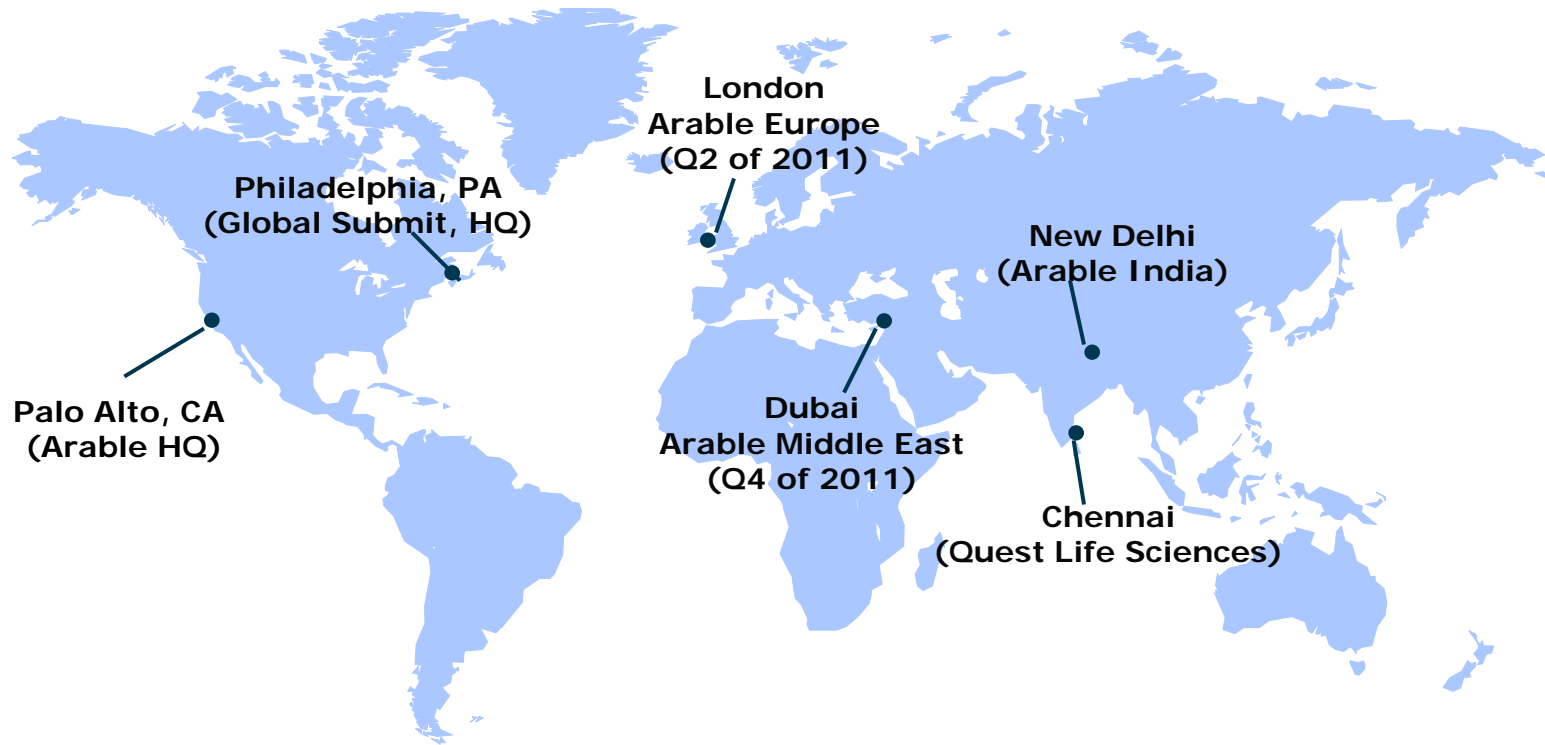


Company Overview

- Arable was founded on principles of cultivating future technologies
- Arable Perform EDC & CTMS Software developed & Validated in 2006
- Large Experienced and knowledgeable staff in Clinical & Regulatory
- 50 Research Scientists full time, CRAs on call, EDC and ETDM
- Premier SITE MANAGEMENT organization
- Large pool of patients and assured time lines
- Our Clinical Research facility is audited and approved by US FDA
- The U.S. FDA and leading life sciences companies use Global Submit's flagship applications, REVIEW™ and VALIDATE™, to review and validate electronic submissions.
- Vast pool of leading hospitals and Principal Investigators most of whom have already done several studies for the USFDA



Global Delivery Capabilities



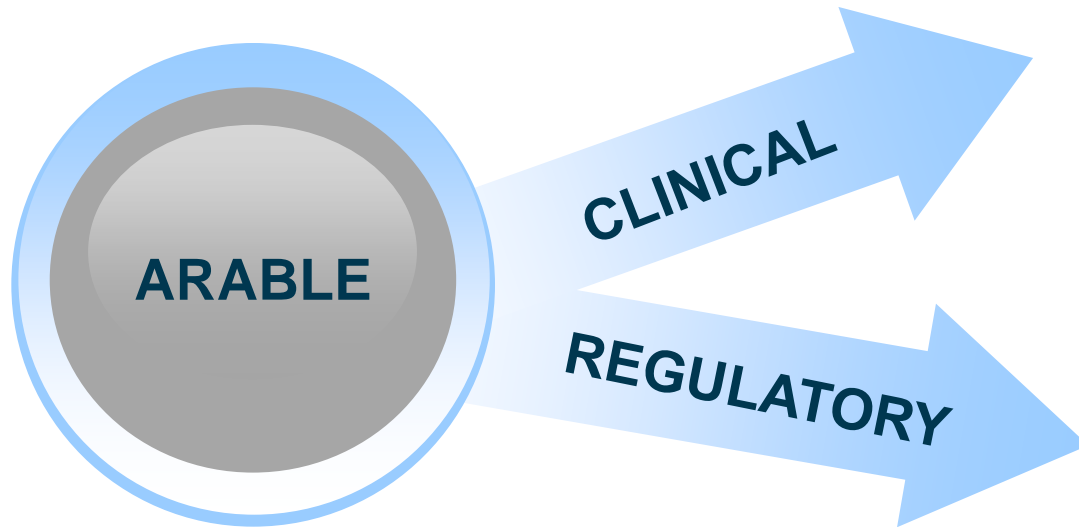
Arable's Differentiators

- Full CRO Services with End-to-end understanding of electronic Clinical & Regulatory process
- Global delivery capability
- Industry leading software
- Rapid solution deployment
- Experienced Management & Delivery Team
- Expertise in electronic submissions & emerging data standards
- US -FDA audited facility for both clinical and bio analytical studies.
- Only Centre in India with 22,000 Sq. ft. area.
- Credibility and strict adherence to ICH guidelines to meet US FDA standards



Products

CTMS tools allow monitors, project managers, data managers, executives, and site personnel to quickly and easily manage multi-site studies. Our **EDC** system offers powerful and innovative features, along with ease-of-use and rollout methods that deliver rapid deployment.



**Arable's
PERFORM**

**GlobalSubmit's
REVIEW
VALIDATE
PUBLISH**

Our regulatory products Review, Validate, and Publish are used exclusively by the FDA and preferred by top pharmaceutical and biotech's worldwide. Our user friendly interface make it fast and easy for pharmaceutical companies to navigate through, organize and submit NDA, IND and other electronic submissions.

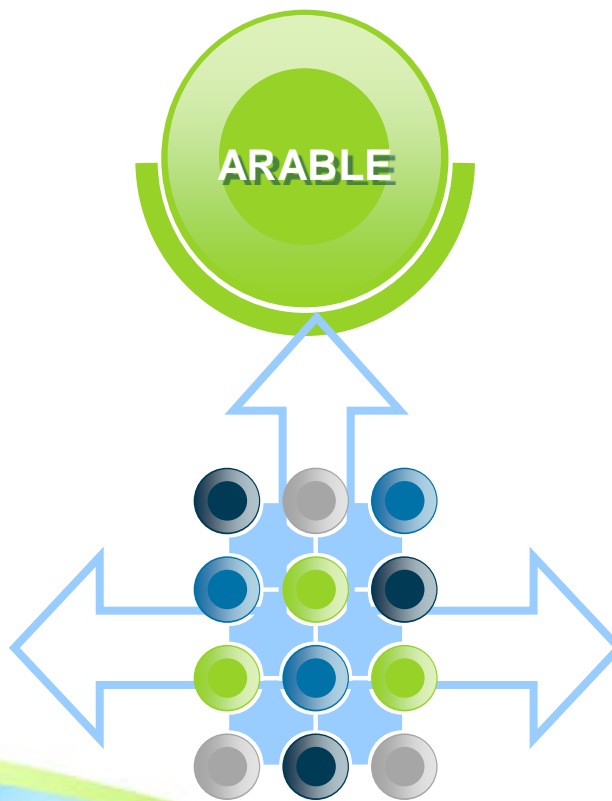


Services Portfolio

Our Clinical Services include training, consulting, study entry, pharmacodynamic services, clinical op services, clinical trial services, project management services, eCRF design besides a whole range of professionally managed services by way of our strategic partnerships with CROs.

Clinical

- Training
- Consulting
- Study Entry
- Pharmacodynamics
- Clinical Op Services
- Clinical Trial Services
- Customer Support
- Project Management
- EDC Study & eCRF Design
- Professional Services



Regulatory

- eCTD Readiness
- Consulting Services
- Electronic Publishing
- Technology Integration
- Rapid Start Implementation
- eCTD Pilot Program
- Training Services
- Data Archiving & Digitization
- eGovernance



EDC & CTMS DEMO



EDC & CTMS System Highlights

- Web-based - no software installation necessary
 - **Perform is built with open source products and standards**
 - **Use any W³C compliant browser or Internet Explorer**
- CTMS & EDC built together in a common platform
- User Administrator able to manage the environment and lexicon
- Document Control and Distribution Included
- Contact Management Included
- Issue and Query Management Included
- Validatable system
 - **Hosted environment specification, IQ and OQ provided to clients**
 - **Human readable audit trail**
 - **21 CFR Part 11, compliant**



EDC System Highlights

- Database built upon principles of SDTM / CDASH
- Block Builder and Page Builder dynamically create eCRF's without programmer or database administrator assistance
- Unique Trial Subject Data Collection Process
- Built-in SDV Process
- Built-in Data Collection Summaries at Trial, Site and Subject levels
- Built-in Data Drill Down and Export at Subject, Site and Trial levels
- De-normalized database structure for Ad-Hoc reports



CTMS System Highlights

- Pre-configured pick-list attributes, admin user modifiable
- Pre-built Base Study Reduces Start-up time up to 70%
- Unique Trial Site Lifecycle Process
- Built-in Trial/Site / Subject status summaries
- Built-in data summaries at Trial, Site and Subject levels
- Document assignment to Trial, Site and Subject levels
- Contacts assignment to Trial, Site and Subject levels



EDC Technical Specifications

- CTMS/EDC/Collaboration platform built on open source industry standard technology
- Rich, responsive browser application functionality based on W³C compliance standards
- Uses Microsoft's powerful localization and internationalization features
- XML based Rules Engine supports complex clinical decision logic and sophisticated dynamic eCRF displays.
- Integrated with Microsoft's Business Intelligence (data analysis) and Reporting Services
- Customer can use graphical Report Designer to build ad-hoc reports.



THE FDA EDGE

- Currently engaged in projects with US FDA.
- In 2005, GlobalSubmit entered into a cooperative research agreement (CRADA) with the U.S. FDA to develop and deliver a comprehensive solution to replace the FDA's Electronic Common Technical Document (eCTD) Viewing System.
- In May 2009, GlobalSubmit announced an agreement with US FDA to develop software that allows the FDA to view, analyze and compare study design information in a unified view.
- In July 2009, GlobalSubmit Signed a Three-Year Maintenance and Support Agreement with FDA to enhance and/or upgrade REVIEW™ and VALIDATE™ software products already being used by the agency.



eCTD Suite Highlights

Developed
For
U.S.FDA

Originally built for Reviewers

100,000+
Sequences
Processed

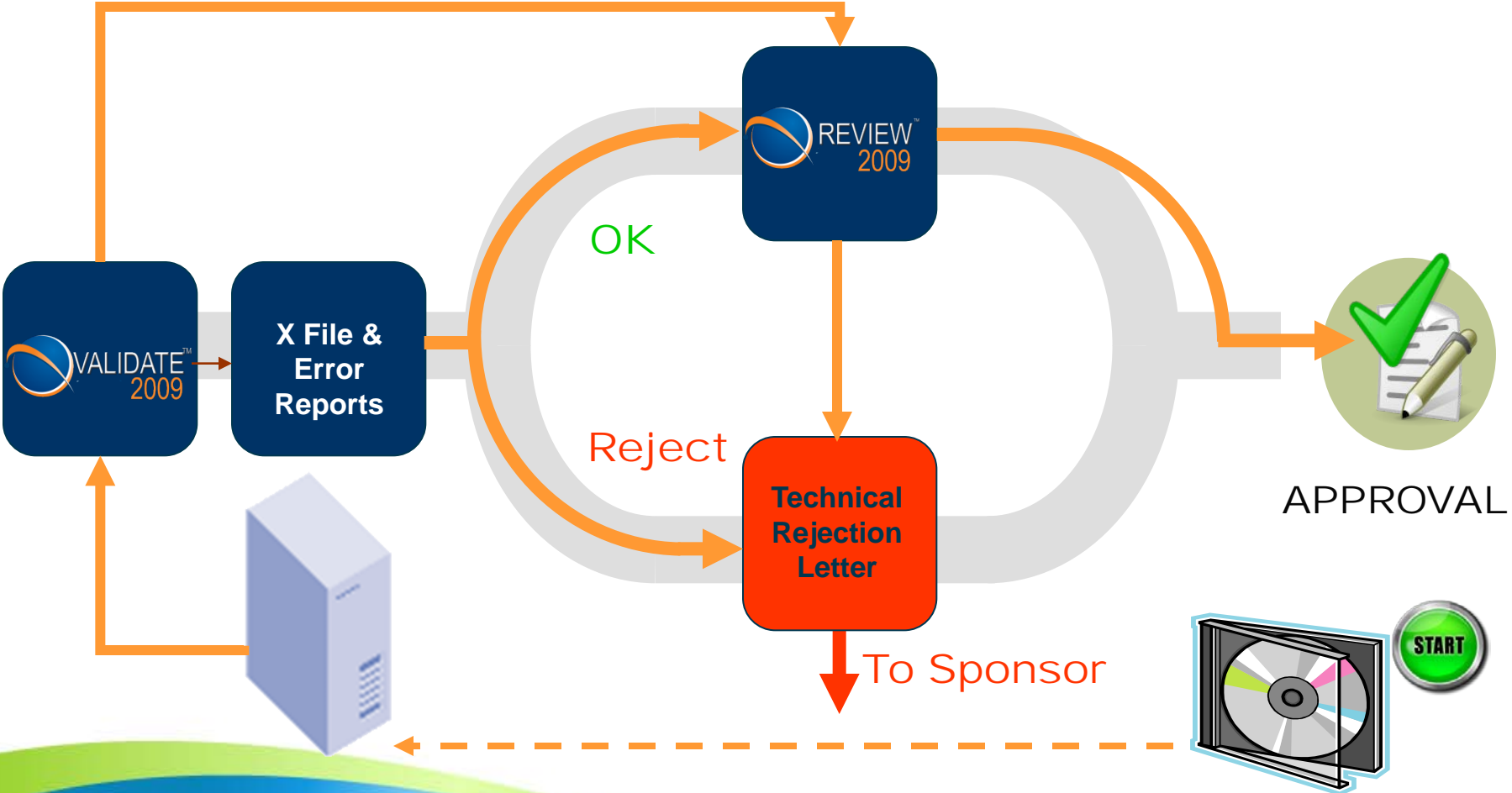
Over 95% of all eCTDs processed worldwide
100% of all eCTDS processed in the US

4,000+
Installations

Most widely used software for eCTD
50% market share
Large, mid and small biopharm customers
Over 50% of customers are multi-nationals



Process Flow – U.S. FDA



Engagement Plan: Solution Delivery

Planning
Phase

- Establish dedicated engagement contact
- Kick-off Conference Call with Study Team
- Develop Project Plan

Implementation
Phase

- Provide On-site and On-line Training
- Provide Product Reference & Training Materials
- Review Status on Periodic Basis through Successful Project Completion

Completion
Phase

- Provide Expert Guidance & Quality Review of Entries
- Follow-Up Assessment; Review On-going Needs

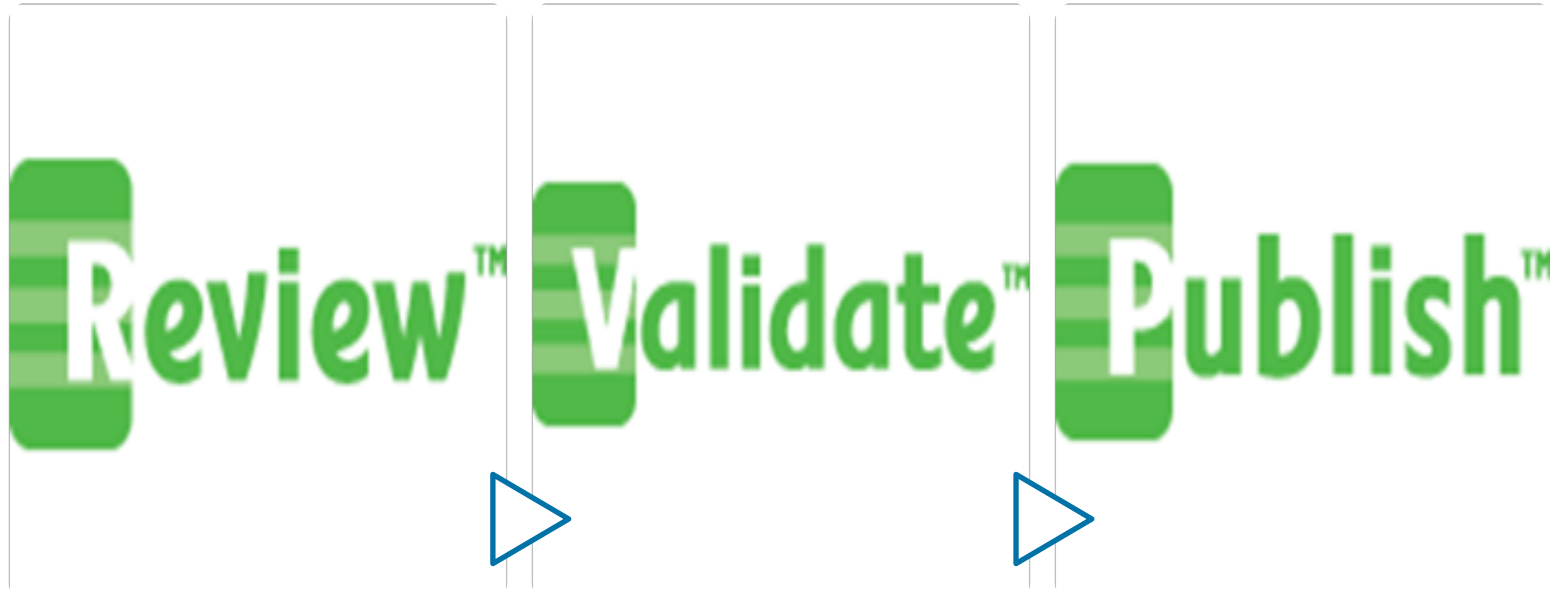


Competitive Advantage

- Proximity to new markets, with offices in India and US.
- Enjoys first mover advantage with major pharmaceutical and sponsors embracing EDC and CTMS solutions.
- Easy to Use.
- Competitively Priced.
- Online platform so cost of hosting takes away from the price point.
- Easily customizable.
- Easy to integrate with existing systems



eCTD Product Suite Demonstration



Regulatory Services Suite

Arable / Global Submit



- eCTD READINESS
- CONSULTING SERVICES
- ELECTRONIC PUBLISHING
- TECHNOLOGY INTEGRATION
- RAPIDSTART IMPLEMENTATION
- eCTD PILOT™ PROGRAM
- TRAINING SERVICES



Thank You!

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Arable

C O R P O R A T I O N

CULTIVATING FUTURE TECHNOLOGY