



How to Choose An IRT for your Clinical Trial

Introduction

Interactive Response Technology (IRT) is the currently accepted term for clinical IVR (Interactive Voice Response) and IWR (Interactive Web Response) systems used in clinical trials. Today's IRT platforms provide complex subject/activity management functionality and robust management of drug supply and shipping throughout the trial.

While IRT technology has gotten increasingly powerful, detailed knowledge of all the functions an IRT can and *should* do has lagged somewhat behind. This white paper was prompted by requests from our clients and colleagues —Sponsors, CROs, and Clinical Suppliers— for a reasonably comprehensive summary of features and issues to consider when vetting IRT systems today. (The first iteration of this updated checklist was published in 2016.)

Veracity Logic (VL), based in North Carolina's Research Triangle area, specializes exclusively in providing interactive response technology supporting clinical trials. The checklist below derives from our decade of experience deploying global systems, including the critical transition years from phone to web. It's a fair statement of the capabilities you can and should reasonably expect from an IRT vendor, and it is our recommended reference guide for issues to consider when selecting *your* IRT provider.

Around the Corner

As of this writing, some cutting-edge capabilities, not yet provided by all or even most IRT vendors, include:

- Forecasting: A step beyond predictive inventory control during a trial, providing advanced planning algorithms for drug manufacture and distribution prior to and during the study
- Mobile compatibility: The ability to access the IRT system on diverse mobile devices and platforms, with no diminishment of look, feel, or capability. Access can be accomplished via internet browser, with best results coming from specialized mobile Apps designed to work with a given IRT system.
- Drug pooling capabilities: The ability to assign drug across protocols, generally controlled by a dashboard-type management tool within the IRT.

Those these items are not included in the following checklist, companies vetting IRT vendors should be sure to initiate conversations on the status of these capabilities and/or plans for implementation in the future.



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How to Choose an IRT – The Checklist

Our suggested list of considerations appears on the following pages.

Checklists like this are living documents; they must be updated as the industry tools progress. Got more items to add to the checklist? Send them to info@veracitylogic.com

Instructions:

Assign a level of importance, or weight, to each requirement in the checklist. The weight indicates the importance of each requirement in your evaluation. There is no "right" weighting for each requirement; each company evaluating IRT vendors may have different categories that they consider important. We suggest using a simple weighting system, such as 1 (low), 2 (medium), and 3 (high).

During your evaluation, place a checkmark in the appropriate vendor column if that vendor or their system meets the requirement. To determine a score for each vendor, count the number of 1s, 2s, and 3s each vendor/system received. You can record the counts in the table at the bottom of the checklist. There you'll also find a table where you can record your observations of each vendor.

IRT Vendor Evaluation Checklist

Vendor 1: _____

Vendor 2: _____

Vendor 3: _____

Issue Category	Requirements	Weight	Vendor 1	Vendor 2	Vendor 3
Vendor Organization	The vendor has demonstrated adequate resources for the Customization and Configuration activities required for timely development of the project system.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The vendor has demonstrated adequate resources for Project Management activities; both during development of the system and after release for use.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The vendor has demonstrated adequate resources for providing Help Desk support while the system is in use.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The vendor has demonstrated adequate resources for providing quality controls during the life of the project – e.g., independence of database production and testing.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Timelines	The vendor has the internal capability to produce a production system in 6-8 weeks from contract to deployment.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Issue Category	Requirements	Weight	Vendor 1	Vendor 2	Vendor 3
Timelines	The vendor supports a 4-week development timeline from finalization of User Requirement Specification (URS) to release of system for Client User Acceptance Testing (UAT).		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The vendor offers a premium option for quicker system deployment, if needed.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The vendor's internal processes promise a maximum of two days for Release to Production (Go Live) after receiving Authorization from the Client.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
System Interface (Overall Look & Feel)	The vendor is willing and able to provide a no-pressure demonstration of their system showing its capability to support a variety of project needs.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Both IVR and IWR options are available.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system integrates data collected in IVR or IWR platform seamlessly and in a timely manner.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system demo shows a clean, user-friendly web interface and simplicity of design.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system has demonstrable, sophisticated functionality.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system has an intuitive layout – e.g., a tabular format – that allows user to see available data ‘at a glance’ (as opposed to requiring queries to retrieve summary data).		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system performs at acceptable speed during the demonstration.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The vendor has confirmed that their system performs on a variety of browsers, including:		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<ul style="list-style-type: none"> • Google Chrome • Internet Explorer • Safari 		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Study Designs	The system supports a variety of study designs, including: <ul style="list-style-type: none"> • Crossover Studies • Sequencing Studies • Extension Studies • Sub-studies 		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
System Configurability	The vendor has designed their system with a focus on configurability and a minimum of custom coding required for project requirements.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Issue Category	Requirements	Weight	Vendor 1	Vendor 2	Vendor 3
System Configurability	The vendor is able to demonstrate the ease of configuring their system.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	End users with appropriate permissions are able to easily reconfigure key settings during the course of a study – e.g., change offset time for drug expiring messages, and modify allowable limits on total number of screened and randomized subjects.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The vendor has provided examples of adequate timeframes for system modifications that do require custom coding by a Developer		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	An adequate spectrum of User Roles/Permission scenarios is standard in the system.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system allows User Roles to be easily re-configured based on project needs.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system allows for client 'Super Users' to be added as needed to the study.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
User Training	The vendor provides an option for training Clinical Research Associates (CRAs or Site Monitors), Investigators, and Study Coordinators during Investigator Meetings.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The vendor provides an option for training study users via online meetings, such as WebEx or GoToMeeting, outside of Investigator Meetings.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The vendor includes an adequate number of training hours in their standard bid.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The vendor provides a TEST area within the system that can be used throughout the study for self-training by client users and for train-the-trainer sessions.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
User Support	The vendor provides help desk coverage 24/7/365.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The vendor provides access to the help desk via both phone and email.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Help desk phone numbers and emails for each country active in the study are readily available for users within the system.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The vendor provides a fast 'self-help' feature for new passwords to be requested by authorized users without requiring help desk intervention.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Issue Category	Requirements	Weight	Vendor 1	Vendor 2	Vendor 3
User Support	The vendor provides User Manuals and Quick Reference Guides for end users.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Users have easy access to user documentation within the system.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The vendor maintains and can share adequate help desk response metrics.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The vendor has a documented escalation plan for unresolved support issues.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21 Part 11 / Annex 11 Compliance	The system uses a two-part login process to identify users, such as a unique UserID (email address, for example) and password.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system supports an easily configurable time frame for password expiration.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system allows easy configuration of the number of failed logins permitted before resetting user accounts.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system allows easy configuration of the number of past passwords that cannot be reused.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system supports an adequate array of notifications related to user passwords, including:		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<ul style="list-style-type: none"> • Initial password on user activation • Password change alerts • Password expiration warnings 				
	The vendor can demonstrate that server uptime in the past three (3) years is greater than 99.9%.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The vendor can demonstrate that adequate maintenance processes are in place.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The vendor can demonstrate adequate backup/restore processes, including:		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<ul style="list-style-type: none"> • Real-time backups (to 'hot' failover server) • Nightly backups • Regular scheduled testing of the backup/restore 				
	The vendor has an adequate disaster response plan, including:		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<ul style="list-style-type: none"> • Formal Disaster Recovery/Response plan • Disaster Communication plan • Roll-over to failover server 				

Issue Category	Requirements	Weight	Vendor 1	Vendor 2	Vendor 3
21 Part 11 / Annex 11 Compliance	The vendor has adequate alerts/notifications when scheduled or unscheduled downtimes occur.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Vendor index of SOPs reflects an adequate understanding of the requirements of 21 CFR Part 11 and European Commission's Annex 11 as they relate to IRT systems.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system includes a full audit trail for clinical data including: <ul style="list-style-type: none"> • Old Value • New Value • Reason for Change • Date/Time of Change • Identifier for the user making the change 		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The vendor has documented Standard Operating Procedures that comply with accepted industry standards		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The vendor has processes in place to prevent deletion of defined data points such as subject unblinding.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Global reach	The system allows users with appropriate permissions to add and update countries throughout the study.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system records activities in the time zone of the site/user.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Translations	The vendor has demonstrated capability to translate phone prompts and system notifications into languages required for the study.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Subject Views	The system allows users to see, at a glance, the status of all subjects in the study.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system provides options for filtering data by site, country, status, etc.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system appropriately restricts user views of data based on each user's permissions, such as the ability to view RandID, Cohort, and/or Strata values.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system allows users to quickly determine each subject's next scheduled activity and expected/target activity date.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system allows users to determine quickly whether subjects are within the window of their next scheduled activity		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Issue Category	Requirements	Weight	Vendor 1	Vendor 2	Vendor 3
Subject Views	The system allows easy configuration of the label used to identify participants in the study (that is, can the label easily be changed to subject, patient, participant, etc.)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system allows for easy configuration of study activities		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Subject Management	The system allows for easy configuration of subject demographics, such as birthdate, age, gender, initials, etc., based on study requirements.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system provides the flexibility necessary to handle data privacy requirements for different countries (such as Germany where collecting full date of birth is not allowed).		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system allows privacy setting to be set at the site level (instead of only at the study level).		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system can assign Subject IDs to subjects added to the system or support allowing users to enter Subject ID.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system supports Subject ID continuity across visits, study phases, or extensions.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system supports identity checks to help prevent confusion or duplication of subjects such as alerts for duplicate birthdate, initials, etc.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system supports subject identity checks within or across sites		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system supports subject identity checks across projects		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system provides a method for users to easily 'drill down' to view all activities recorded for and drug assigned to a subject.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system provides an intuitive method for users to easily add/enroll subjects.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Issue Category	Requirements	Weight	Vendor 1	Vendor 2	Vendor 3
Activities Management	The system supports recording the following activities (at a minimum and as needed for the study): <ul style="list-style-type: none"> • Screen/enroll subject • Scheduled activities (such as randomization, drug assignments, completion, follow-up) • Unscheduled activities (such as screen failure, discontinue/early terminate/withdrawal, unscheduled resupply of drug to subject) • Emergency unblinding 		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system supports recording reasons for activities – e.g., screen failures, early withdrawals after randomization, etc.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system can easily configure and reconfigure user permissions to edit subject and activity data.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system allows for Skipped Visits (allowing scheduled visits to be skipped)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system allows for a scheduled visit to occur without the accompanying drug assignment slated for that visit, and maintains subject status on return		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Randomization	The system supports a variety of randomization schema, including: <ul style="list-style-type: none"> • Static • Stratified (by single or multiple variables) • Dynamic/Minimization • Forced • Adaptive 		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Randomization options are available via both web and phone (based on project needs)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system can easily configure custom eligibility and other randomization-related questions required for the study.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system provides controls for which users are able to record subject randomization.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system supports easy importing of key data throughout the study – e.g., randomization, users, sites, kits, etc.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Issue Category	Requirements	Weight	Vendor 1	Vendor 2	Vendor 3
Randomization	The vendor has a backup process for providing manual randomization of subjects in the event clinical sites are unable to access the system.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system permits Subject Recovery (rescreening a subject with the same ID)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system permits Subject Replacement (replacing early withdrawers in a randomization scheme)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Subject Unblinding	The system provides users with appropriate permissions an easy-to-use mechanism for unblinding subjects when necessary, including web and phone options		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Authorization Codes	The system provides a mechanism for requiring users to receive permission from a higher level prior to performing certain actions – e.g., recording an activity out of window, unblinding, age deviation, etc.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cohort Management	The system supports simultaneous or concurrent activation of multiple cohorts		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system permits users to activate and deactivate cohorts as needed throughout the study		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Limits	The system supports users updating/changing limits to the number of screened and randomized subjects throughout the study.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system supports users setting subject limits at key levels, including: <ul style="list-style-type: none"> • For the entire study • For each country • For each site • For each treatment group • For each strata (if applicable) • For each cohort (if applicable) 		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Subject Diaries	The system offers a user diary component.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system has diary compliance reporting capabilities		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system can generate reminders/outbound calling on varying schedules.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Shipment Management	The system supports an alert "trigger" inventory control system based on site-level inventory levels (such as initial shipment quantities, target baseline quantities, and trigger quantities).		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Issue Category	Requirements	Weight	Vendor 1	Vendor 2	Vendor 3
Shipment Management	The system allows for individual numbered kits AND ancillary/supplemental materials to be tracked in inventory.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system allows ancillary supplies to be ordered via the system <i>without</i> inventory tracking.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system supports a "predictive" inventory control solution based on active subjects and allowing drug wastage to be minimized in cases of tight supply.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system supports a "just-in-time" option for drug allocation from central warehouse and/or depot		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system allows for global, regional depots		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system allows for multiple central warehouses		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system allows for different CTM types to be sourced from different warehouses/depots		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system allows users with appropriate permissions to manage the list of Kit Batches used in the study		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system allows users with appropriate permissions to manage the list of Regions, in which countries with sites participating in the study are located.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system allows for <i>both</i> automatic and manual shipment requests		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system supports assigning different methods for generating shipment requests (such as Manual Only, Automated, or Predictive) to be assigned at the site level.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system maintains a history of Shipment Requests, Distribution (Sends), Receipts, and Cancellations for each site		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system supports the ability of designated users to cancel shipment requests.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system supports Direct to Subject shipments.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system has robust methods of determining when drugs approaching expiration may be included in a shipment request..		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Issue Category	Requirements	Weight	Vendor 1	Vendor 2	Vendor 3
Shipment Management	The system supports the application of site enrollment thresholds which permit different drug resupply levels for hi, medium and low enrolling sites.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CTM (kit) Management	The system supports a variety of labels for drug containers (e.g., kit, bottle, vial, etc.) to accommodate the needs of the project.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system easily supports importing CTM data throughout the study.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system allows for both planned and available (manufactured) kits to be tracked.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system supports unscheduled CTM assignment to subjects throughout the study.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system allows users to report real-life problems within the system – e.g., damaged kits, missing kits, kits declared unusable for other reasons, expiring kits, misadministered kits.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Drug Accountability	The system supports Drug Accountability at both the unit (kit) level and/or the kit contents level.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Content level accountability includes the number returned, number used, and number missing.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system allows sites to generate Return shipments for returning unused drug to warehouses and/or depot.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system allows users to track drug destruction at clinical sites and/or warehouses and depots.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system permits redistribution of returned study drug to the same subject.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Temperature Deviation	The system supports tracking deviations from temperature requirements (e.g., frozen, refrigerated, and/or ambient) for each drug type used in the study.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system quarantines CTM with temperature deviations until they can be reviewed.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Issue Category	Requirements	Weight	Vendor 1	Vendor 2	Vendor 3
Temperature Deviation	The system allows users to designate CTM involved with temperature deviations to remain available/unavailable for assignment to subjects after review.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system allows for uploading temperature deviation (e.g., temp-tale) curves at the kit level.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Dose Management	The system supports flexible dosing schedules that are easily configured on a project basis – e.g., simple and complex Dose Escalation and Titration schedules accommodated at a Subject level.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system is able to calculate subject dosing based on preset criteria – e.g., weight.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system allows Manual titration with up/down changes of one or more dosing steps.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Site Management	The system allows users with appropriate permissions to add, activate, deactivate, and update site information during the study.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
User Management	The system allows users with appropriate permissions to add, activate, deactivate, and update user information during the study.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Summary Reports	The system provides an acceptable array of standard reports.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system enables users to easily export data in a format readable by a variety of data analysis tools (such as MS-Excel and SAS) for custom/ad hoc reporting.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system supports sending standard data exports to a client's secure FTP server.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system provides, within the system, easily accessible summary/rollup data on subject, activities, and CTM assignments.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Data Imports	The systems allows users with appropriate permissions to import data into the system throughout the study		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The ability to import data including (at a minimum): <ul style="list-style-type: none"> • Subject Randomization Schema • Kits, batches, regions • Sites • Users 		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Data Exports	The vendor is able to provide separate blinded and unblinded data exports.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Issue Category	Requirements	Weight	Vendor 1	Vendor 2	Vendor 3
Data Exports	The vendor has a process for sending encrypted/password protected data files. To client FTP server		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system provides periodic (nightly, weekly, etc.) exports of blinded:		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<ul style="list-style-type: none"> • Subject Data • Activity Data • CTM (Kit) Data 		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system has sufficient flexibility in configuring export schedules to meet study needs.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The vendor provides end-of-study exports of unblinded:		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<ul style="list-style-type: none"> • Subject Data • Activity Data • CTM (Kit) Data • Subject Randomization Data • Audit Trail Data 		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The vendor can provide fully customized data exports for the study.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Data Integrations	The system supports data integration/transfer with a variety of EDC, CTMS, and ePRO systems.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The vendor has experience sharing data with your specific EDC and/or ePRO systems		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	System integration options include scheduled and transactional/real-time data transfers.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system supports automated data imports from special 3 rd party systems, such as lab results.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The vendor has documented processes for data integrations and creation of Data Transfer Specifications		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
System Alerts, Messages, and Notifications	<p>The system produces an adequate set of standard notifications, generated when:</p> <ul style="list-style-type: none"> • Subject activities are recorded • Shipments are requested, sent, or received • Subject, Activity, Shipment, or Kit data is modified • Alerts (for missed subject visits, late shipment receipts, expiring drug, etc.) • Site and User changes • User Credentials (and changes to passwords) 		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Issue Category	Requirements	Weight	Vendor 1	Vendor 2	Vendor 3
System Alerts, Messages, and Notifications	The system supports immediate generation of notifications.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system supports periodic/delayed generation of notifications.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Users can choose to access notifications via email or directly within the system		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Users can designate a secondary email or group email for notifications		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system retains notifications for review throughout the study.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system supports sending blinded and unblinded notifications with controls based on user permissions.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system employs a system of notifications based on user roles, easily reconfigured for each study.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system allows new users to view notifications appropriate for their user role that were created before the user was added to the system.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Notification content is easily customized to meet study needs.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IVR (phone) Interface	The vendor has existing toll free (for site users) phone service for IVR access for all of the countries required by the project		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The IVR (phone) interface includes, at minimum, capabilities to:		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<ul style="list-style-type: none"> • Add a subject • Randomize a subject • Record scheduled activities • Perform an emergency unblind • Receive a shipment 		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Changes made using the IVR (phone) immediately reflected in the IWR (web) and vice versa		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	The system prevents conflicts when two users change the same subject data using the phone and the web simultaneously in projects utilizing both IVR and IWR		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Record the count of requirements having a weight of 1, 2, or 3 for each vendor.

Vendor Name	Count 1s	Count 2s	Count 3s

Record your observations about each vendor in the table below:

Vendor Name	Observations

Selected IRT Vendor:

We're making this checklist available as a tool to help Sponsors, CROs, Clinical Suppliers, and others evaluate IRT vendors. If you have suggestions for requirements we should add to future versions of the checklist, please send them to info@veracitylogic.com. Thank you.