



# CHOOSING YOUR CLINICAL IRT PARTNER IN 2021



## About Veracity Logic

Veracity Logic (VL), based in North Carolina's Research Triangle area, specializes in providing subject and inventory management systems using interactive response technology (IRT) to support our clients' clinical trials. At Veracity Logic, we're as proud of our ability to manage the real-life demands of clinical trials as we are of our technology. When you work with us, you'll find that we are reliable, responsive and user friendly --we support your trial with our experienced, helpful team that is dedicated to your success.

## Introduction

This vendor selection checklist 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 vendors and systems today.

We've developed this checklist using our fifteen years of experience deploying global systems, including the critical transition years from phone to web. It contains many of the capabilities you can reasonably expect from an IRT vendor, and it is our recommended reference guide for issues to consider when selecting *your* IRT provider. We certainly hope you find it useful.

If you find you have comments or additional items you'd like to see included in future checklists, please send them to [info@veracitylogic.com](mailto:info@veracitylogic.com).

## Choosing an IRT Vendor - The Checklist

### 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"/> |

| Issue Category                         | Requirements   | Weight | Vendor 1                 | Vendor 2                 | Vendor 3                 |
|--|--|--------|--------------------------|--------------------------|--------------------------|
| 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"/> |
|  | 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 IWR (web) and IVR (phone) options are available for ePRO (that is, Subject Diaries).  |        | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
|  | The system integrates data collected in the 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 users 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 vendor has confirmed that their system performs on a variety of browsers, including: <sup>1</sup> <ul style="list-style-type: none"> <li>• Google Chrome™</li> <li>• MICROSOFT EDGE</li> <li>• Mozilla Firefox</li> <li>• Apple Safari®</li> </ul> |        | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

<sup>1</sup> All trademarks are the property of their respective owners.

| Issue Category         | Requirements   | Weight | Vendor 1                 | Vendor 2                 | Vendor 3                 |
|------------------------|--|--------|--------------------------|--------------------------|--------------------------|
| Study Designs          | <p>The system supports a variety of study designs, including:</p> <ul style="list-style-type: none"> <li>• Crossover Studies</li> <li>• Sequencing Studies</li> <li>• Extension Studies</li> <li>• Sub-study Tracking</li> </ul> |        | <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"/> |
|                        | 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., "turn on" a cohort, 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"/> |
| User Training          | The vendor provides an option for training Clinical Research Associates (CRAs or Site Monitors), Investigators, and Study Coordinators at 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"/> |
| User Training          | 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"/> |

| Issue Category                   | Requirements   | Weight | Vendor 1                 | Vendor 2                 | Vendor 3                 |
|----------------------------------|--|--------|--------------------------|--------------------------|--------------------------|
| User Support                     | 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"/> |
|                                  | The vendor provides User Manuals and or Quick Reference Guides for end users.  |        | <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 re-used.   |        | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
|                                  | The system supports an adequate array of notifications related to user passwords, including: <ul style="list-style-type: none"> <li>Initial password on user activation</li> <li>Password change alerts</li> <li>Password expiration warnings</li> </ul> |        | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
|                                  | 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"/> |

| Issue Category   | Requirements  | Weight   | Vendor 1                 | Vendor 2                 | Vendor 3                 |
|--|---|--|--------------------------|--------------------------|--------------------------|
| 21 Part 11 / Annex 11 Compliance                                 | The vendor can demonstrate adequate backup/restore processes, including: <ul style="list-style-type: none"> <li>Real-time backups (to 'hot' failover server)</li> <li>Nightly backups</li> <li>Regular scheduled testing of the backup/restore</li> </ul>     |  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
|  | The vendor has an adequate disaster response plan, including: <ul style="list-style-type: none"> <li>Formal Disaster Recovery/Response plan</li> <li>Disaster Communication plan</li> <li>Roll-over to failover server</li> </ul>                             |  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
|  | 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"> <li>Old Value</li> <li>New Value</li> <li>Reason for Change</li> <li>Date/Time of Change</li> <li>Identifier for the user making the change</li> </ul> |  | <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"/> |
| 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"/> |

| Issue Category     | Requirements  | Weight | Vendor 1                 | Vendor 2                 | Vendor 3                 |
|--------------------|---|--------|--------------------------|--------------------------|--------------------------|
| 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"/> |
|                    | 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"/> |



| Issue Category        | Requirements  | Weight | Vendor 1                 | Vendor 2                 | Vendor 3                 |
|-----------------------|---|--------|--------------------------|--------------------------|--------------------------|
| Subject Management    | 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"/> |
| Activities Management | The system supports recording the following activities (at a minimum and as needed for the study): <ul style="list-style-type: none"> <li>• Screen/enroll subject</li> <li>• Scheduled activities (such as randomization, drug assignments, completion, follow-up)</li> <li>• Unscheduled activities (such as screen failure, discontinue/early terminate/withdrawal, unscheduled resupply of drug to subject)</li> <li>• Emergency unblinding</li> </ul> |        | <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"/> |

| Issue Category      | Requirements   | Weight | Vendor 1                 | Vendor 2                 | Vendor 3                 |
|---------------------|--|--------|--------------------------|--------------------------|--------------------------|
| Randomization       | The system supports a variety of randomization schema, including: <ul style="list-style-type: none"> <li>• Static</li> <li>• Stratified (by single or multiple variables)</li> <li>• Dynamic/Minimization</li> <li>• Forced</li> <li>• Adaptive</li> </ul> |        | <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"/> |
|                     | 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"/> |

| Issue Category      | Requirements   | Weight | Vendor 1                 | Vendor 2                 | Vendor 3                 |
|---------------------|--|--------|--------------------------|--------------------------|--------------------------|
| Cohort Management   | 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"> <li>• For the entire study</li> <li>• For each country</li> <li>• For each site</li> <li>• For each treatment group</li> <li>• For each strata (if applicable)</li> <li>• For each cohort (if applicable)</li> </ul> |        | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Subject Diaries     | The system offers a user diary component via web or telephone access.  |        | <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"/> |
|                     | 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"/> |

| Issue Category       | Requirements   | Weight | Vendor 1                 | Vendor 2                 | Vendor 3                 |
|----------------------|--|--------|--------------------------|--------------------------|--------------------------|
| Shipment Management  | 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"/> |
|                      | 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"/> |

| Issue Category        | Requirements   | Weight | Vendor 1                 | Vendor 2                 | Vendor 3                 |
|-----------------------|--|--------|--------------------------|--------------------------|--------------------------|
| CTM (kit) Management  | 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, mis-administered kits. |        | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
|                       | The system allows users with appropriate permissions to edit CTM information.  |        | <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"/> |
|                       | 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"/> |

| Issue Category  | Requirements  | Weight | Vendor 1                 | Vendor 2                 | Vendor 3                 |
|-----------------|---|--------|--------------------------|--------------------------|--------------------------|
| 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"> <li>• Subject Randomization Schema</li> <li>• Kits, batches, regions</li> <li>• Sites</li> <li>• Users</li> </ul> |        | <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: <ul style="list-style-type: none"> <li>Subject Data</li> <li>Activity Data</li> <li>CTM (Kit) Data</li> </ul>   |        | <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: <ul style="list-style-type: none"> <li>Subject Data</li> <li>Activity Data</li> <li>CTM (Kit) Data</li> <li>Subject Randomization Data</li> <li>Audit Trail Data</li> </ul> |        | <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, ePRO, and Central Lab 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 <sup>rd</sup> 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"/> |

| Issue Category   | Requirements  | Weight                   | Vendor 1                 | Vendor 2                 | Vendor 3                 |
|--|---|--------------------------|--------------------------|--------------------------|--------------------------|
| System Alerts, Messages, and Notifications                     | The system produces an adequate set of standard notifications, generated when: <ul style="list-style-type: none"> <li>• Subject activities are recorded</li> <li>• Shipments are requested, sent, or received</li> <li>• Subject, Activity, Shipment, or Kit data is modified</li> <li>• Alerts (for missed subject visits, late shipment receipts, expiring drug, etc.)</li> <li>• Site and User changes</li> <li>• User Credentials (and changes to passwords)</li> </ul> |                          | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
|  | 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"/> |



| Issue Category        | Requirements   | Weight | Vendor 1                 | Vendor 2                 | Vendor 3                 |
|-----------------------|--|--------|--------------------------|--------------------------|--------------------------|
| IVR (phone) Interface | The IVR (phone) interface includes, at minimum, capabilities to: <ul style="list-style-type: none"> <li>• Add a subject</li> <li>• Randomize a subject</li> <li>• Record scheduled activities</li> <li>• Perform an emergency unblind</li> <li>• Receive a shipment</li> </ul> |        | <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:

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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](mailto:info@veracitylogic.com). Thank you.