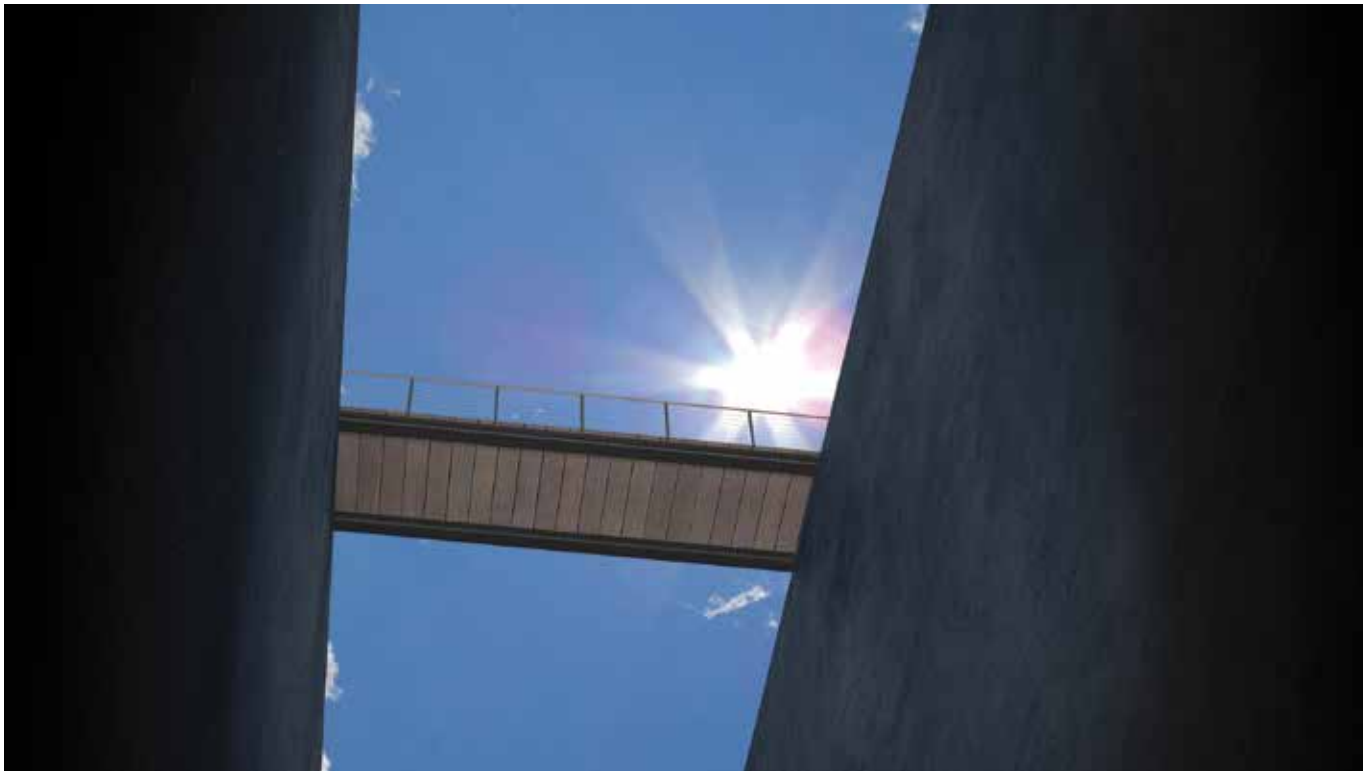


RTSM/IRT: A Roadmap For Developing Systems That Address Current Frustrations

The technology behind the randomization of patients and the supply management of study drugs is vital to conducting safe, scientifically rigorous, clinical trials. This technology, commonly known as Randomization and Trial Supply Management (RTSM) or Interactive Response Technology (IRT), has saved drug developers time and resources by automating critical tasks. However, as the pressure to get drugs to market faster continues to mount, and clinical trials continue to grow in complexity, with exponentially more data becoming available, existing RTSM and IRT solutions are coming up short.

Anecdotal reports indicate an increasing disconnect between the needs of study teams and the capabilities of existing RTSM and IRT solutions. Yet, until today, there has been a lack of quantitative research that pinpoints exactly where the frustrations lie.

A recent survey administered to professionals in clinical operations, trial management and related functional areas, with direct involvement in RTSM/IRT sought to address this knowledge gap. The survey focused on uncovering areas for improvement in IRT by asking professionals about their experiences with current RTSM/IRT systems, frustrations that arise when using the technologies, and where opportunities for improvement exist.

75%

of respondents agreed that integration with other clinical platforms was the biggest issue they face.

The results reflected the anecdotal feedback from the market and validated the current challenges study teams face. The study revealed that clinical operations teams struggle with technologies that are difficult to integrate with other clinical platforms and require significant customization, which must be done by the technology vendor to meet their needs. Respondents said these shortcomings delay studies, ultimately slowing the time it takes to bring drugs to market, while also negatively affecting the numbers of clinical trials they can conduct.

Collectively, the results paint a picture of a sector that has evolved faster than the technologies upon which it relies. More importantly, the data also provides a roadmap to a brighter future, in which self-service capabilities enable clinical operations teams to take back control, empowering them to run faster, more efficient clinical trials.

Frustrations With Today's RTSM/IRT Systems

The first step on the path to that better future state is to understand how today's RTSM/IRT systems are not meeting expectations and, in fact, are hampering study teams' ability to conduct clinical trials efficiently. To gather these insights, the survey asked respondents to identify the challenges associated with their current RTSM/IRT solutions. Three key areas emerged as the most common challenges.

92%

indicated they have to make changes to their IRT systems due to study changes.

Of the respondents, 75% agreed that integration with other clinical platforms was the biggest issue they face. RTSM/IRT solutions had traditionally been standalone technologies, distinct from other eClinical systems. But, vendors soon began trying to integrate their offerings to streamline workflows, in response to customer needs. The survey finding suggested years of work to integrate RTSM/IRT solutions into broader eClinical platforms have failed to yield the simple plug-and-play connectivity users want.

Integration isn't the only challenge users face. The survey also indicates that there are inherit issues within the RTSM/IRT solutions themselves. Of the respondents, 71% indicate that a lack of flexibility and inability to support study changes is a top pain point.

Additionally, the survey identified that more than two-thirds (66%) of respondents found the review and validation process, the time needed to build, test and deploy technologies, and reliance on vendors to perform these tasks as leading challenges associated with their current RTSM/IRT solution.

Subsequent survey questions delved into how these previously mentioned challenges affect clinical trial professionals. A question about study changes — an area seventy one percent (71%) of people called challenging — revealed why this is such an obstacle. Of the respondents, ninety two percent (92%) indicated they have to make changes to their IRT systems due to study changes and sixty four percent (64%) said changes need to be made two or more times. Not only that, these changes to the RTSM/IRT system require going back to the vendor, which tacks on additional time and cost to the trial.

Many of these changes cover the sort of relatively minor amendments that are part and parcel of working in the dynamic clinical trial environment. For instance, half of respondents listed the addition or removal of visits and changes to inclusion criteria among their most commonly requested changes. (*See exhibit 1*)

The need to rely on vendors to make changes – even simple changes such as those described above – several times during a trial adds to study timelines that are already prolonged by the initial RTSM/IRT setup process. Based on the survey results, on average, it takes six and a half weeks to build, deploy, and validate an RTSM/IRT solution. In some cases, the process takes more than 10 weeks, according to respondents. These timelines ultimately increase the overall time it takes to conduct a therapeutic trial and, by extension, the length of time patients must wait to access the medicine.

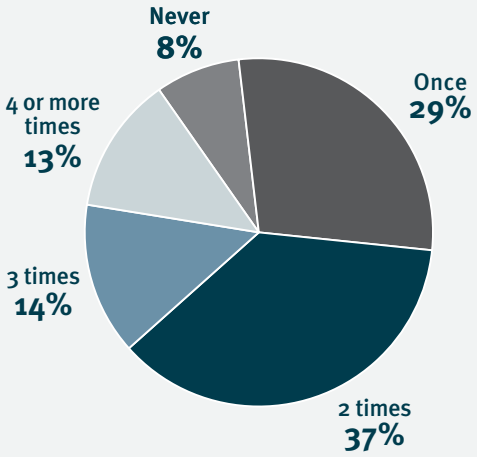
How To Address RTSM/IRT Pain Points

Identification of these pain points provides a broad roadmap for the development of RTSM/IRT systems that better meet the needs of today's study teams. The survey goes on to address the path forward and

Exhibit 1

Study Changes: Average Frequency & Most Commonly Requested

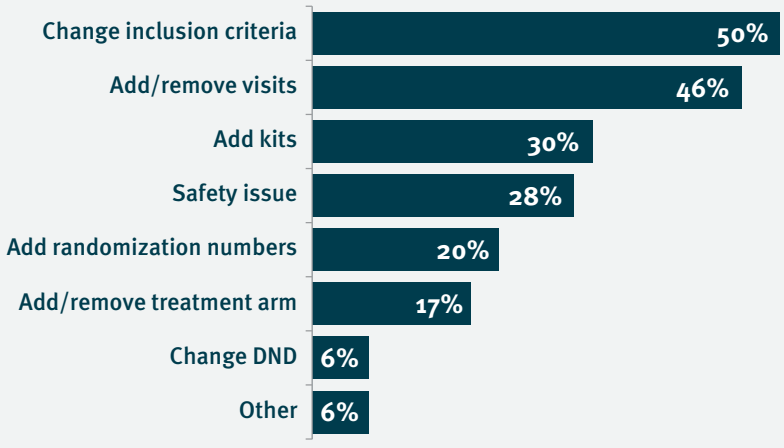
Number of times per study (on average) changes are requested of RTSM/IRT vendor



Question: For an average study, how many times do you go back to your RTSM/IRT vendor for study changes? Base = All qualified respondents (n=254).

Due to rounding percentages add up to 101%.

Most commonly requested mid-study changes



Question: What are the most commonly requested mid-study changes? (Select up to three.) Base = All qualified respondents; up to three answers permitted (n=254).

how leveraging this feedback to develop more suitable RTSM/IRT solutions will have a positive impact on randomization and trial supply management in future clinical trials. One-third of survey respondents listed the integration of RTSM/IRT solutions into eClinical platforms as the biggest change they expect to see over the next five years, suggesting there is confidence that vendors are on the cusp of succeeding in their long-running efforts to bring technologies together.

Given the survey found that, today, integration with other technology is the most challenging aspect of RTSM/IRT solutions, there is reason to hope that these advancements in RTSM/IRT technology will have far-reaching effects on the speed and efficiency of clinical development programs.

The top three benefits expected from RTSM/IRT becoming part of a larger eClinical platform are simplified integration, elimination of data duplication, and easier study set-up. These benefits were ranked very closely together, indicating that there are several, equally important benefits expected from merging RTSM/IRT into a broader eClinical platform. (*See exhibit 2*)

The two most commonly-cited benefits of making an RTSM/IRT function part of a larger eClinical platform were simplified integration and easier set-up. As indicated by the survey questions regarding frustrations with today's RTSM/IRT solutions, integration into eClinical platforms will have significant positive impact on clinical study teams. In addition to integration or inclusion into eClinical platforms, most respondents identified accelerated trial builds and the emergence of completely self-service RTSM/IRT solutions as some of the biggest changes likely to happen over the next five years.

The RTSM/IRT Systems Of Tomorrow

Efforts to bring the capabilities of RTSM/IRT systems in line with the needs of users will take place against a backdrop of ongoing technological and therapeutic advancements. These broader trends will affect the day-to-day tasks of clinical trial professionals and extend the boundaries of what eClinical technologies can achieve. As such, vendors should pay attention to these shifts to ensure the capabilities of technology being developed today meets the future needs and expectations of users.

More than half of respondents cited that an increase in the use of mobile app technology in clinical trials will have the most impact on RTSM/IRT systems over the next five years. This broader technological shift from enterprise desktop software to mobile apps is already affecting multiple parts of the pharmaceutical industry, and it has specific implications for RTSM/IRT systems in clinical trials.

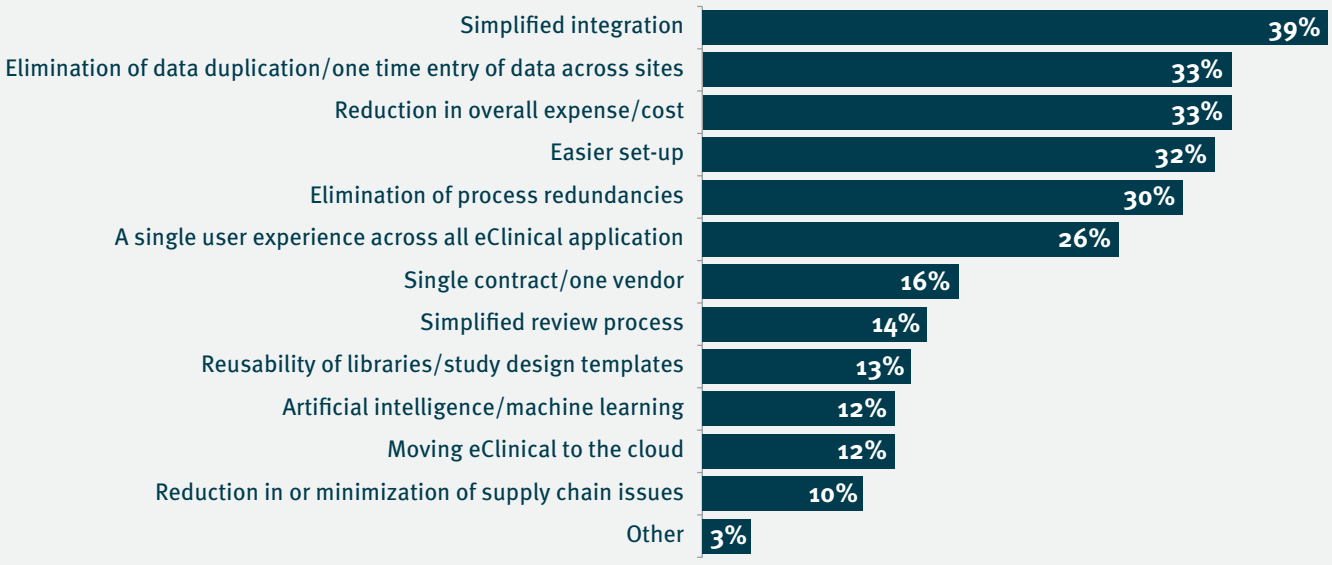
Equipped with an RTSM/IRT mobile app, clinical trial site staff could simplify multiple aspects of the study drug management process. Instead of manually entering information whenever drugs arrived, were dispensed, or were returned, site staff could use the camera on their mobile device to scan the barcode associated with the package.

Barcodes can contain a wealth of information on the medication kit to which they are associated. As such, scanning the barcode could enter all the required information into the RTSM/IRT system.

This app-enabled approach is more convenient for busy site staff and, in speeding up data entry, cuts the likelihood of administrative backlogs forming at the center. Its implications are bigger and more important than that, though. By reducing the risk of data entry errors, the app would also improve patient safety by ensuring that trial participants receive the right medication. And finally, instead of spending their

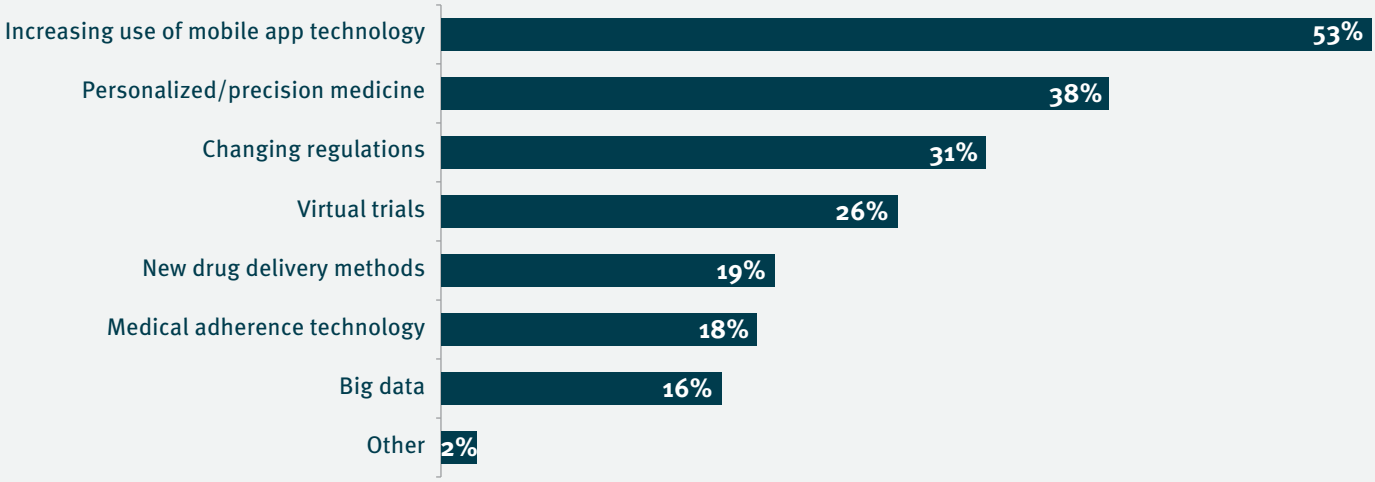
Exhibit 2

Top Three Benefits Expected from IRT in an eClinical Platform



Base = All qualified respondents familiar with eClinical Platforms; up to three answers permitted (n=238).

Exhibit 3
Advances In Clinical Trials With The Most Impact On IRT - Next 5 Years



Question: Which advances in clinical trials will impact IRT the most in the next 5 years?
Base = All qualified respondents; multiple answers permitted (n=254)

valuable time entering data, site staff can spend more time doing what they do best, which is taking care of patients.

All of the technology needed to create such a system exists — and is likely within arm's reach — today. The same could not have been said 10 years ago, a fact that raises the question of what technologies will be reshaping RTSM/IRT systems a decade from now. In looking out across a five-year horizon, the survey respondents zeroed in on precision medicine and changing regulations as the two other advances that will most affect RTSM/IRT. (*See exhibit 3*)

Both trends are starting to reshape clinical trials and the technologies that underpin them. Precision medicine trials enroll small, molecularly-defined subpopulations of patients. This changes the nature of clinical trials.

To find patients, sponsors may need to activate sites outside of the typical research hotspots. The number of subjects per site is often very low, and for precision medicine studies, randomization is likely unnecessary. These factors change the demands on RTSM/IRT solutions.

Developing The RTSM/IRT Systems Users Want

It is unclear exactly how these trends will play out and what specific effects they will have on the use of RTSM/IRT systems.

While some thoughtful predictions and customer feedback will still be needed to design technologies that are perfectly adapted to these trends, as a result of these findings, the roadmap is much clearer in many areas. The survey data unequivocally shows where gaps exist between the needs of today's users and the capabilities of current RTSM/IRT solutions. The challenge now is to close the gap.

Study teams are frustrated with the lack of integration among their clinical systems, the amount of time it takes to build, test and deploy studies, as well as lack of flexibility and ability to support study changes. eClinical vendors who address these challenges will help to usher in an era of faster, more efficient clinical trials. In response to the needs of the market, as voiced in this survey, technology vendors should innovate to improve system flexibility, while empowering study teams with self-service capabilities that allow them to take back control, from trial design to making mid-study changes.

Such improvements in technology will better support the clinical trials of today and significantly speed clinical development for tomorrow. This will cut the time it takes for innovative therapies to reach patients, which is, ultimately, the shared goal of everyone in the industry.