Veeva 2017 Unified Clinical Operations Survey: Annual CRO Report

The *Veeva 2017 Unified Clinical Operations Survey: Annual CRO Report* examines contract research organizations' (CROs) progress in unifying clinical operations. It represents the experiences and opinions of CRO respondents from around the world. The goal of the research is to understand the drivers, barriers, and benefits of a unified clinical operating model from a CRO perspective. It also explores the current state of collaboration among CROs and sponsors and the industry's progress overall to streamline clinical systems and processes.

Executive Summary

Findings indicate an industrywide move toward a unified clinical model. This modern approach is defined by end-to-end processes and systems, seamless collaboration between all internal and external stakeholders, and greater metrics-driven insights delivered across the clinical lifecycle to improve performance.

- 100% of CRO respondents report the need to unify their clinical applications, including their CTMS, EDC, and eTMF. For a majority, this is driven by the need to speed study execution, realize cost savings, improve study quality, and gain greater visibility.
- CROs use more applications than sponsors to manage clinical trial processes. Half (50%) of CROs use five applications or more to manage clinical trials, versus 38% of sponsors.
- Most (72%) CROs say integrating multiple applications is the biggest challenge they face with their clinical solutions. Half (54%) see the need for better visibility and 30% have clinical data tracked outside of their systems.
- Respondents also cite significant challenges stemming from application and process silos. Half (50%) say the challenge of integrating their EDC and CTMS applications limits their organization's ability to improve clinical operations.
- Sponsors and CROs alike see partner collaboration as a major focus area. Yet one in four (24%) CROs say their clinical applications limit partner collaboration versus 33% of sponsors.

- Consistent with the drive to streamline collaboration and implement end-to-end processes, CROs are moving away from manual systems. More than a third (42%) now use an eTMF application, double the number reported in 2014. Only 8% of CROs say their clinical operations departments use paper for most/all TMF documents, down from 47% in 2014.
- CROs are more inclined than sponsors to use data to improve their study processes, with 35% extensively using it versus 27% of sponsors. CROs that extensively use data to improve clinical trial processes achieve significant benefits, including better visibility into performance metrics (59%) and automated tracking/reporting of documents (65%).

Drivers and Barriers to Unifying Clinical Systems

With clinical trial outsourcing predicted to exceed 70% by 2020[1], CROs are under tremendous pressure to increase study execution and quality against a backdrop of increasing complexity across the clinical lifecycle. This has prompted industrywide recognition of the need for a unified clinical model that is defined by end-to-end processes and systems, seamless collaboration across the clinical ecosystem, and greater insights from metrics to increase performance.

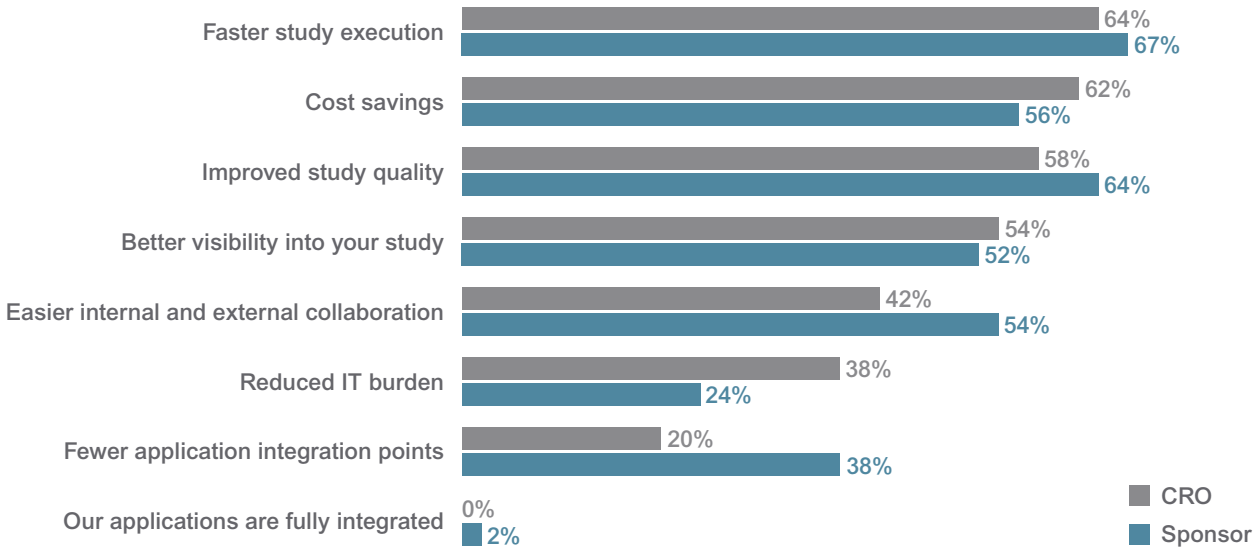
All (100%) CRO respondents report the need to unify their clinical applications. The top three most important drivers for unifying clinical applications are faster study execution (64%), cost savings (62%), and improved study quality (58%). It is not surprising that cost savings rank higher for CROs than sponsors (56%) as containing costs is necessary to deliver competitive advantage. Reducing the burden on IT resources to support and maintain multiple systems is an important cost containment strategy, with more than a third (38%) of CROs versus less than a quarter (24%) of sponsors citing the need to reduce IT burden as a key driver for unification.

Segmenting CRO survey respondents into the top CROs in the industry versus others reveals some variation in drivers for unification. The top CROs manage about 50% of the $25 billion clinical CRO market[2] in terms of revenue – which increases their need for more tools to help improve visibility and insights across the clinical trial landscape. As such, the top CROs report better study visibility as a driver (86%) versus less than half (42%) of other CROs.

[1] Pharmatimes.com. Trials and Tribulations. April 2017.
[2] Clinicalleader.com. Surveying The Clinical CRO Market & Outsourcing Landscape. July 2017.

Top Drivers of Unification

Base: CRO and sponsor respondents, N=253



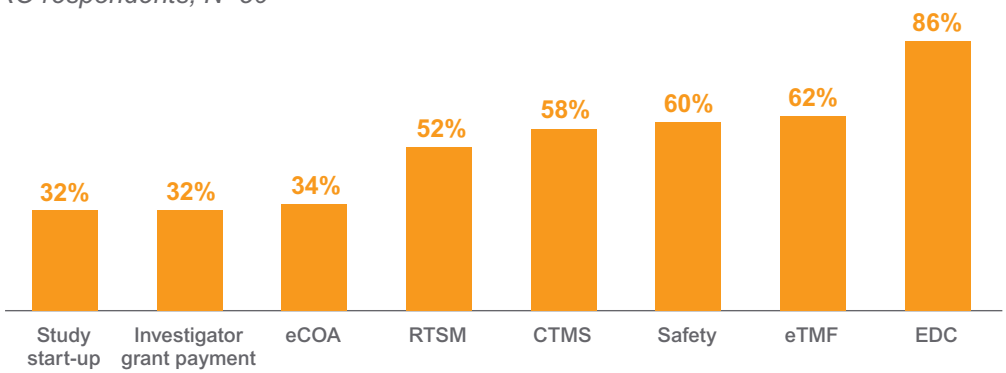
To the degree your organization needs to better integrate/unify the clinical applications identified in question 3 (e.g., CTMS, EDC, eTMF, etc.), what are the most important drivers? Select all that apply. (Q.5)

On average, CRO respondents use four third-party applications to manage their clinical studies and half (50%) use at least five applications. Sponsor, consultant, and CRO respondents use four applications on average and just over a third (38%) use five or more. The top CROs use an average of five applications and more than a quarter (29%) use eight applications. Given the siloed nature of clinical systems, it's not surprising to see the number of applications used increase with the number of trials executed.

The most commonly used applications reported by CROs are EDC (86%), eTMF (62%), and safety (60%).

Applications Used to Manage Clinical Studies

Base: CRO respondents, N=50



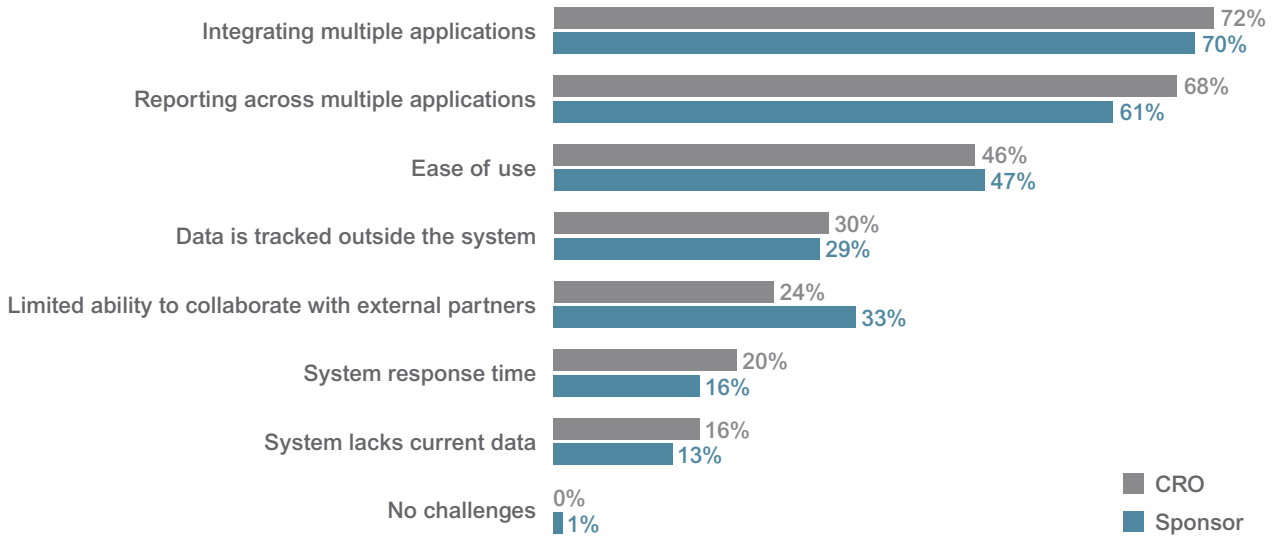
Does your organization utilize applications developed by third-party vendors in managing clinical studies? If yes, please indicate which are currently in use. (Q. 3)

Nearly all (96%) CRO respondents have at least one major challenge with their clinical applications, and most (82%) report two or more challenges. The top two issues for CROs – integrating multiple applications (72%) and reporting across applications (68%) – are a direct result of clinical application silos. Sponsors also rank these issues as top challenges (70% and 61%, respectively).

The next most often reported challenges are ease of use (46%) and data tracked outside the system (30%). When data is tracked elsewhere, the number of manual processes to capture, analyze, and generate reports increases which, in turn, negatively impacts usability and makes collaboration more difficult; an issue reported by 24% of CROs and 33% of sponsors.

Biggest Challenges with Clinical Applications

Base: CRO and sponsor respondents, N=253



What are the biggest challenges, if any, your organization faces in utilizing the clinical applications identified in question 3 (e.g., CTMS, EDC, eTMF, etc.)? Select all that apply. (Q.4)

Challenges in Managing Collaborative Clinical Processes

According to the Tufts Center for the Study of Drug Development,[3] it takes one year, on average, to identify a site and activate it to conduct research. Additionally, Tufts also recently found that study start-up time is no faster today than it was nearly 10 years ago.[4] Consistent with this research, 96% of CROs report challenges with the study start-up process, an area that's heavily reliant on collaboration with external parties.

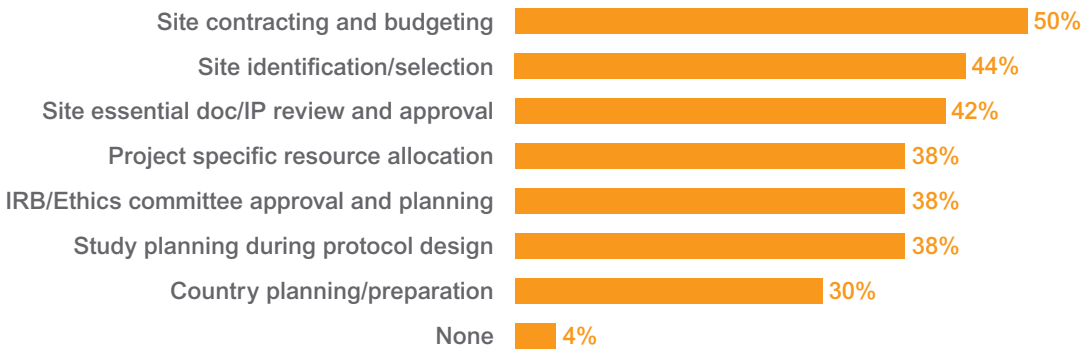
[3] Lamberti, MJ, Chakravarthy, R, Getz, KA. Assessing Practices & Inefficiencies with Site Selection, Study Start-Up, and Site Activation. Applied Clinical Trials, August 2016.
[4] Clinicalinformaticsnews.com. A new start for study start-up. June 2017.

The time from the pre-study visit to contract execution accounts for most of the study start-up cycle time, according to further Tufts research.[5] Contracting and budgeting is a significant issue for CROs and sponsors. Half (50%) of CROs and 60% of sponsors say site contracting and budgeting is one of the most challenging study start-up processes for their organization. Further segmentation of this group reveals 79% of the top CROs see site contracting and budgeting as a challenge, reflective of the number and complexity of trials they run. Most (60%) sponsors also see contracting and budgeting as a key challenge.

The next most often cited study start-up challenges for CROs are site identification/selection (44%) and essential document/IP review and approval (42%).

Most Challenging Study Start-up Processes

Base: CRO respondents, N=50



What are the most challenging, if any, study start-up processes for your organization? Select all that apply. (Q.14)

Spreadsheets, clinical trial management systems (CTMS), and eTMF are among the most commonly used tools to manage the study start-up process. Spreadsheets are used by 72% of CRO respondents and 48% use a CTMS application. Almost two-thirds (64%) of the top CROs report using an eTMF application for study start-up versus 33% of CROs. Although CTMS and eTMF applications are used by some CRO respondents to aid study start-up, neither are purpose-built to handle the complexity of the study start-up process.[6] The predominant use of spreadsheets is likely to contribute to the collaboration challenges reported by both CROs and sponsors.

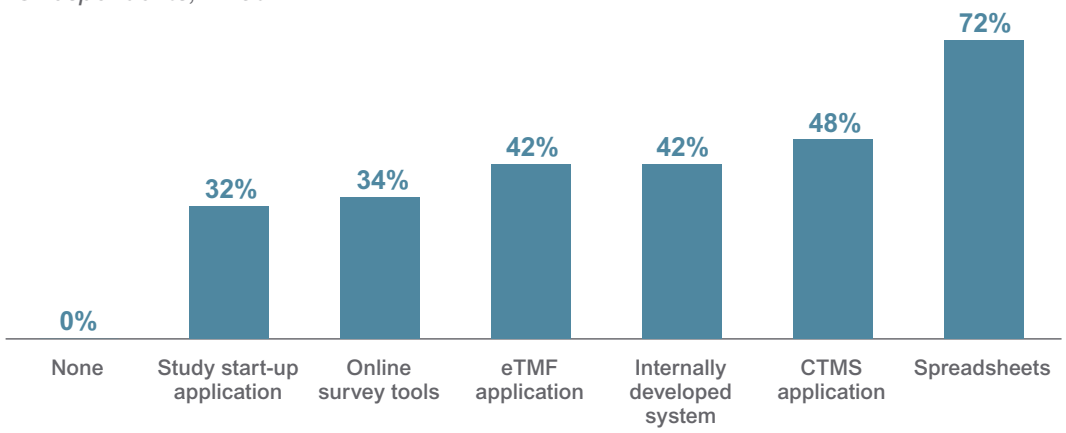
Although purpose-built study start-up applications are relatively nascent, they are more widely used by CROs than sponsors (32% versus 9%). Further segmentation of CRO respondents shows 71% of the top CROs use a study start-up application compared to 17% of other CRO respondents.

[5] Lamberti, MJ, Brothers C, Manak D, Getz, KA. Benchmarking the study initiation process. Therapeutic Innovation & Regulatory Science, 47(1) 101-109. 2013.Applied Clinical Trials, August 2016.

[6] Applied Clinical Trials. A New Approach to an Old Problem – Speeding Study Start-up. June 2016

Tools Used to Manage Study Start-up Processes

Base: CRO respondents, N=50

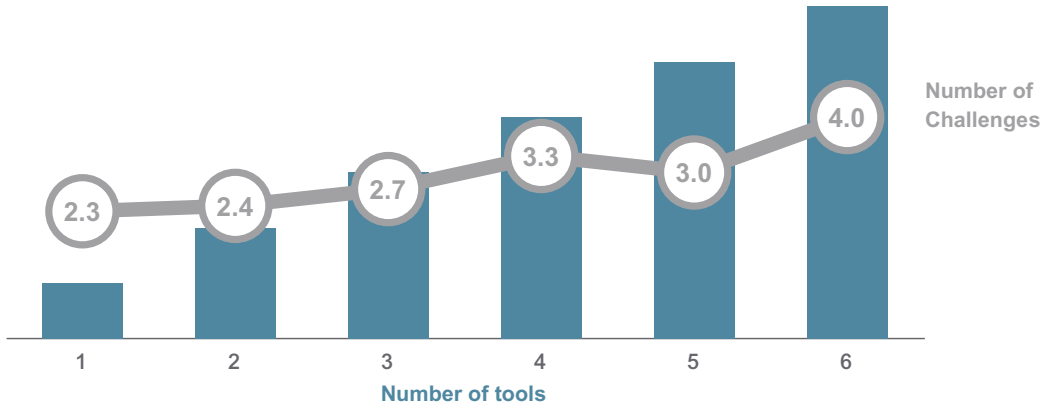


What tools do you use to manage study start-up processes? Select all that apply. (Q.15)

Like sponsors, the more tools a CRO uses to support the study start-up process, the more challenges they report in study start-up. On average, CROs use three tools to manage the study start-up process and have an average of three challenges.

Number of Challenges with Study Start-up Processes by Number of Tools Used

Base: CRO respondents, N=50



What tools do you use to manage study start-up processes? Select all that apply. (Q.15)
What are the most challenging, if any, study start-up processes for your organization? Select all that apply. (Q.14)

Impact of CTMS Applications on Clinical Operations

Highlighting the importance of CTMS applications to clinical operations, life sciences organizations are expected to increase their CTMS investments by almost 15% each year through 2020, driven by rising demand for data and site collection solutions and the availability of new CTMS applications.[7]

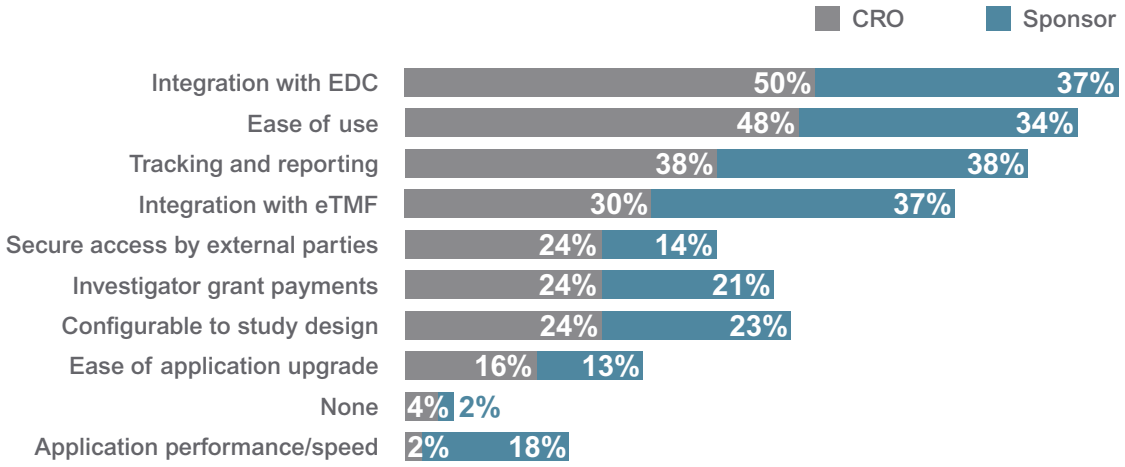
Nearly all (96%) CROs say challenges with their current CTMS application limit their ability to improve clinical operations. Integration with EDC (50%), ease of use (48%), and tracking and reporting (38%) are the most frequently reported issues. Sponsors agree tracking and reporting (38%) and ease of use (34%) are top challenges, although in slightly fewer numbers than CROs. This is consistent with CROs being heavier users of CTMS applications as sponsors outsource more clinical trial management activities to them.

CROs' need for CTMS/EDC integration is also greater than sponsors (50% versus 37%, respectively) which may be a result of sponsors outsourcing their CRA role to CROs, therefore reducing their need for an in-house CTMS.

The top CROs say integration with eTMF also limits their ability to improve clinical operations (64% versus just 17% of other CROs).

Challenges with CTMS Applications that Limit Ability to Improve Clinical Operations

Base: CRO and sponsor respondents, N=253



What challenges, if any, do you have with your organization's CTMS application that limit your ability to improve clinical operations? Select all that apply. (Q.7)

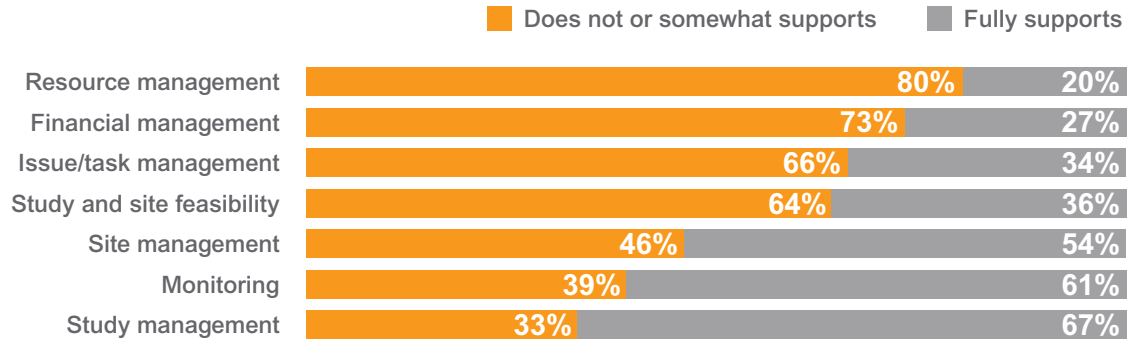
In addition, CROs report significant deficiencies with their CTMS applications including an inability to fully support key functions like resource management (80%), financial management (73%), issue/task management (66%), and study and site feasibility (64%).

[7] Markets and Markets. eClinical Solutions Market, Global Forecast to 2020. 2016.

Despite CTMS deficiencies, CROs are nevertheless gaining greater benefits than sponsors with the majority reporting site management (54%), monitoring (61%), and study management (67%) as fully supported by their CTMS application.

Processes Supported by CTMS Applications

Base: CRO respondents, N=50



To what degree does your organization's CTMS application support the following processes? Check only one box per row. (Q.6)

eTMF Adoption and Maturity

eTMFs are the second most frequently used applications to manage clinical studies, after EDCs. Types of eTMF applications used range from more general-purpose content management systems to purpose-built applications.

CROs and sponsors use a variety of eTMF solutions. The least mature solutions, such as local file systems and cloud file shares, provide simple storage and archival of TMF documents and are typically referred to as 'passive' TMFs. Content management systems are slightly more mature, but often have limited accessibility and are not designed for TMF processes. The most mature solutions are purpose-built eTMF applications. Designed specifically to manage TMF documents and unify end-to-end processes, these 'active' solutions manage information and processes in real-time as the TMF is being generated.

Over the past three years, CROs have seen substantial increases in benefits achieved from using active eTMF applications. Most CROs (81%) using an active eTMF application report improved audit and inspection-readiness, up 24 percentage points from 57% in 2015. The next most cited benefit is automated tracking at 76%, up 33 percentage points from 43% in 2015, followed by improved central remote auditing (up 30 percentage points from 36% to 66%).

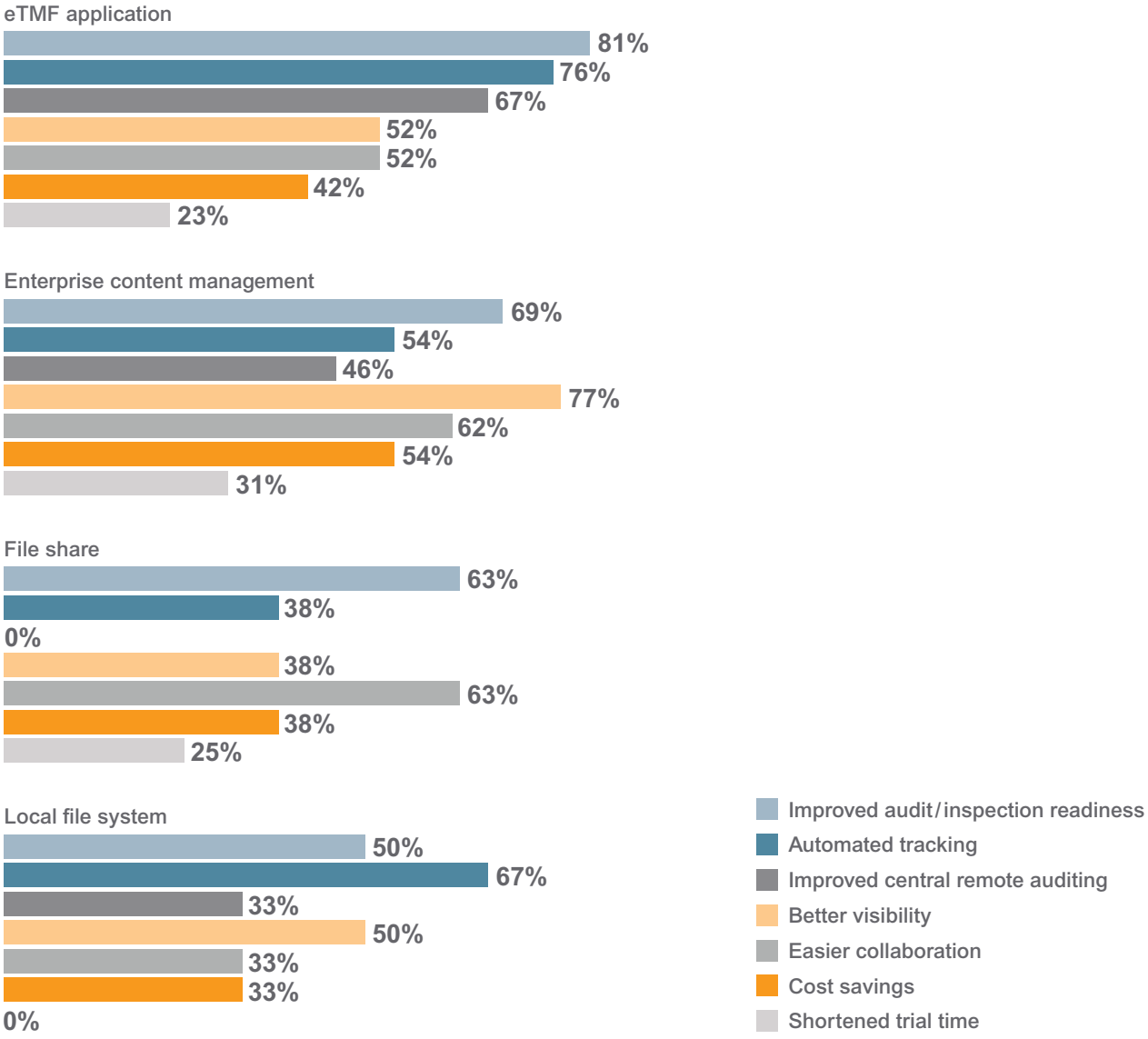
Automation, centralized oversight, visibility, and use of metrics drive efficiencies and collaboration that help clinical operations teams better manage the increasing volume and complexity of modern clinical trials.

Additionally, those that use a purpose-built eTMF application report a higher number of benefits achieved versus those who use paper (4 benefits to 0, respectively).

Regardless of eTMF solution used, CROs report more benefits across the board than sponsors. Better visibility, for example, is reported as a benefit by 54% of CROs versus 38% of sponsors.

Benefits of an eTMF by Type of eTMF

Base: CRO respondents, N=50



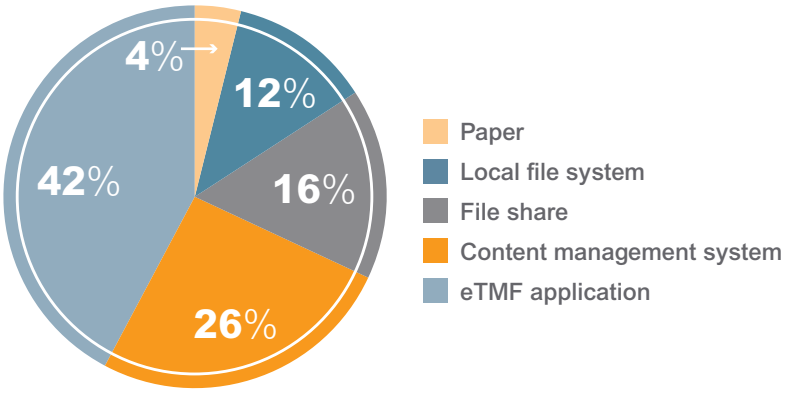
What benefits were achieved with your organization's implementation and use of the eTMF solution specified in question 12? Select all that apply. (Q.13)

This research shows there has been a major move away from 'passive' systems to 'active' eTMF solutions as 42% of CROs now use a purpose-built eTMF application, double the number reported in 2014 (21%). A third (31%) of sponsors have moved to a purpose-built eTMF application, up from just 13% in 2014.

In the same timeframe, use of enterprise content management systems is down from 33% to 26%, with local file share down from 26% to 12%. Cloud file share is also down from 21% in 2014 to 16%.

eTMF System Used

Base: CRO respondents, N=50



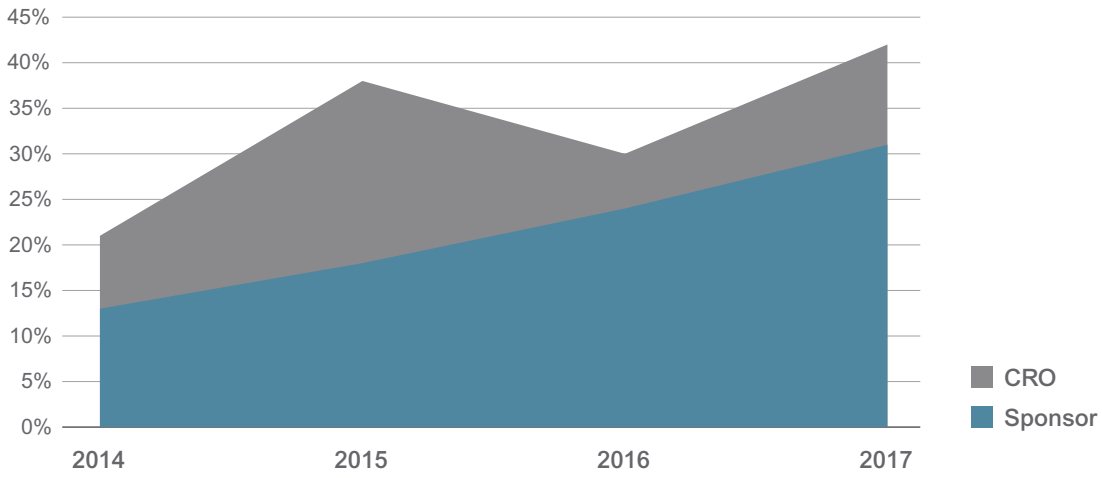
What type of eTMF solution do you currently use? Select only one. (Q.12)

The increase in the use of eTMF applications coincided with the MHRA's 2014 update to its definition of critical GCP inspection findings to include trial master files that are inaccessible or sufficiently incomplete such that inspectors cannot fulfill their duties.[8] This correlates with CROs reporting improving audit and inspection readiness as a key driver for eTMF adoption.

[8] Medicines and Healthcare products Regulatory Agency. The Medicines for Human Use (Clinical Trials) Amendment Regulations. Regulation 31A 1-3. 2014

eTMF Application Use 2014-2017

Base: CRO and sponsor respondents, 2017 N=253, 2016 N=180, 2015 N=186, 2014 N=161



What type of eTMF solution do you currently use? Select only one. (Q.12)

The Move Away from Manual Systems and Processes

Consistent with the drive to unify clinical processes and improve visibility, CROs have significantly decreased their use of paper over the past four years.

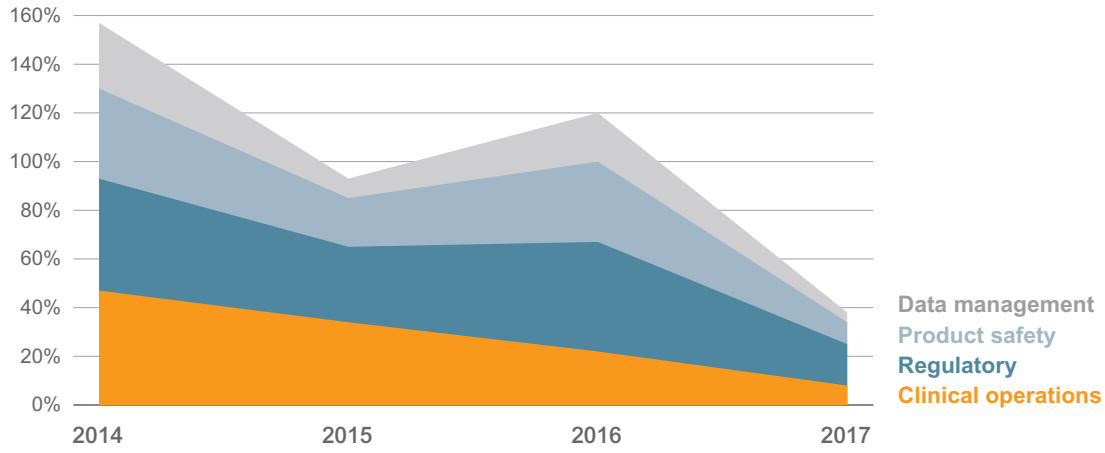
Clinical operations departments led the way, with just 8% of CROs reporting that most to all TMF documents managed by clinical operations departments are on paper, a drop of 39 percentage points since 2014. Given more than half of the documents in the trial master file are managed by clinical operations, this underscores the potential impact of this reduction.

Regulatory takes a close second, with CROs reporting a drop of 29 percentage points since 2014 in the number of most to all TMF documents managed on paper, and product safety followed, recording a 28 percentage point drop in the same time period.

Sponsors report similar reductions across almost all functional areas measured.

Most to All Documents Managed on Paper at Some Point in Their Lifecycle

Base: CRO respondents, 2017 N=50, 2016 N=49, 2015 N=50, 2014 N=43



In each of the following areas, how many of your organization's TMF documents are managed on paper at any point during their lifecycle? Select only one box per row. (Q.9)

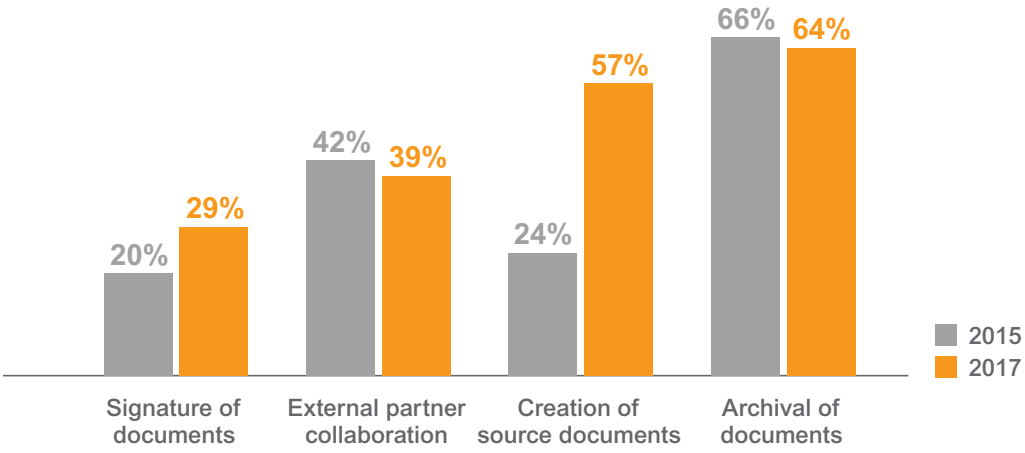
Correspondingly, decreases in the use of paper to manage TMF documents were matched by increases in more automated methods including the electronic creation of source document templates, which has more than doubled since first reported in 2015 (57% in 2017 versus 24% in 2015). Over the same period, the use of electronic signature for documents grew by nine percentage points to 29%.

Almost two thirds (64%) of CROs electronically archive TMF documents; a similar level to 2015. Electronic collaboration with external parties has also remained around the same in this timeframe at 39%.

Sponsors report a similar level of activity, although the same four areas have all increased for this group since 2015, with the creation of source documents more than doubling from 25% to 52% in that time.

Activities Mostly or Always Done Electronically

Base: CRO respondents, 2017 N=50, 2015 N=50



To what extent is your organization currently doing any of the following with TMF documents? Check only one box per row. (Q.11)

Collaboration with External Partners

ContractPharma's 2016 Outsourcing Survey found increasing demand for outsourcing and nearly all life sciences companies surveyed view their relationship with their contract service providers as a true partnership.[9]

As a result of increased outsourcing, collaboration between sponsors and CROs is critical in a unified clinical environment. A quarter (24%) of CROs say limited ability to collaborate with external partners is a challenge with their current clinical applications; a third (33%) of sponsors agree.

Today 40% of CROs say they use eTMF to exchange documents with sponsors, yet only 19% of sponsors say the same. Similarly, 52% of CROs report collaborating via portals, versus 31% of sponsors. These findings indicate there is room for improvement in collaboration for both CROs and sponsors.

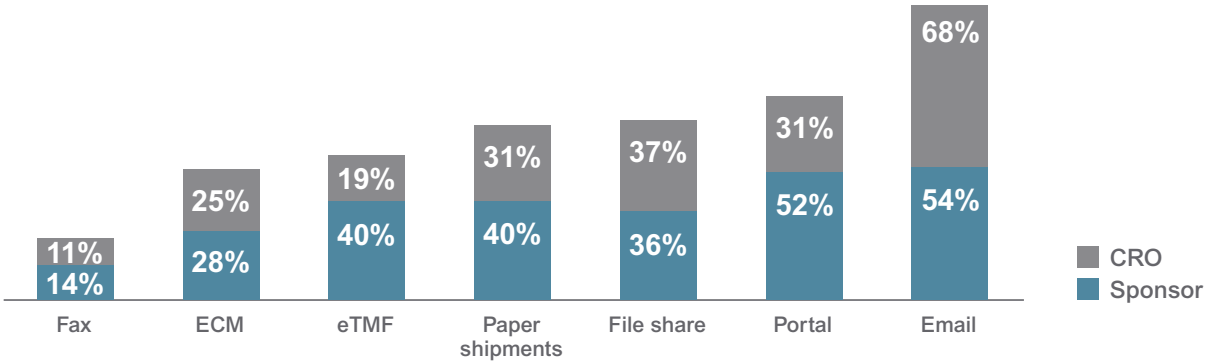
[9] ContractPharma. 2016 Annual Outsourcing Survey, May 2016.

The most prevalent method of TMF document exchange with partners is email used by 54% of CROs and 68% of sponsors. Although CROs have reduced their email use, down 26 percentage points since 2014 (from 80% to 54%), emailing documents puts information outside of controlled processes, making it harder to track and collaborate efficiently.

Consistent with the decrease in most or all documents managed on paper at some point in their lifecycle, CROs have reduced paper shipments of TMF documents by 25 percentage points since 2014. CROs are also ahead of sponsors with their use of eTMF applications to exchange documents, with an increase of 16 percentage points (from 24% to 40%) since 2014.

Methods to Exchange TMF Documents Between Sponsors and CROs

Base: CRO and sponsor respondents, N=253



What methods does your organization use to exchange TMF documents with external parties? Select all that apply per row. (Q.8)

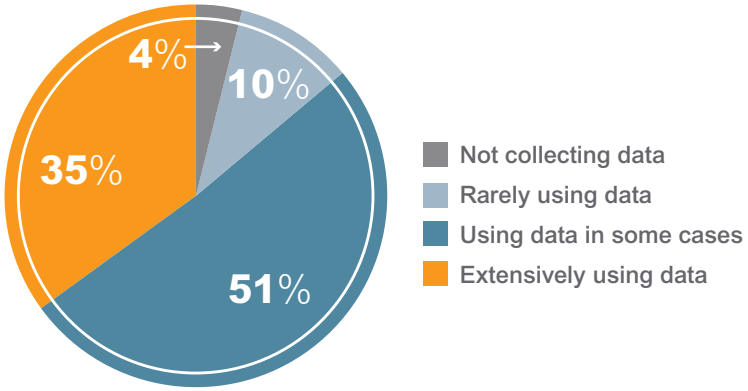
Use of Data to Improve Study Processes

Integrating and reporting across multiple applications are the biggest challenges CROs face when asked about their use of clinical systems (72% and 68%, respectively). In addition, half (54%) state better study visibility is one of the most important drivers for unifying their clinical applications.

Overall, CROs use more data than sponsors, with a third (35%) extensively using it versus a quarter (27%) of sponsors. Despite this fact, 14% of CROs are not using or rarely use data to improve study processes, with just over a third only using it in some cases. This could be reflective of issues with the collection and analysis of real-time data due to information and system silos.

Organizations Using Data to Improve Study Processes

Base: CRO respondents, N=50

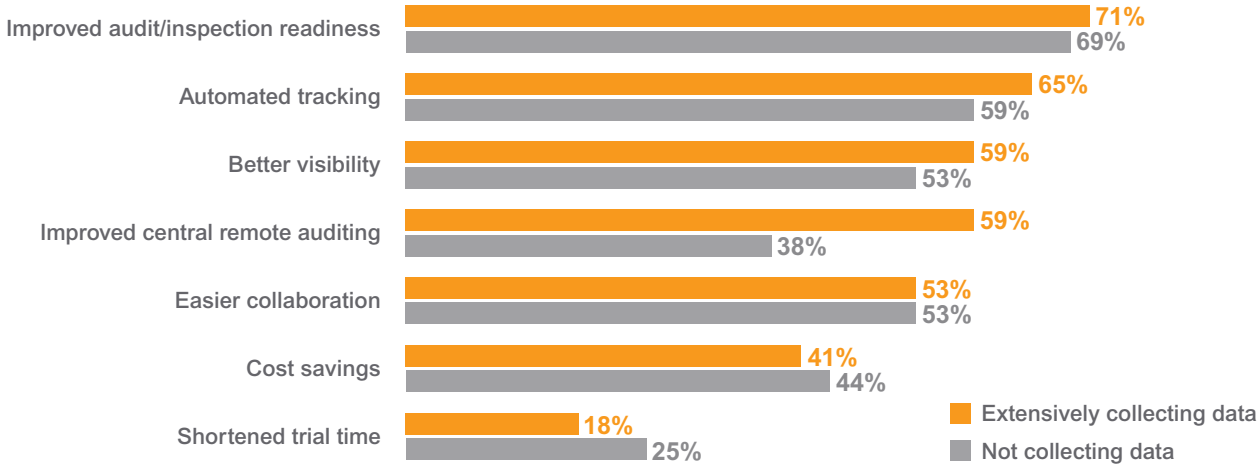


To what extent is your organization leveraging data (e.g., time from initial review to approval) to improve study processes? Select one of the following. (Q.16)

In addition, eTMF users extensively using data report the largest improvements in almost all of the areas surveyed, including better visibility into performance metrics (59%) and automated tracking/ reporting of documents (65%).

eTMF Benefits Achieved by Level of Metrics Usage

Base: CRO respondents, N=50



To what extent is your organization leveraging data (e.g., time from initial review to approval) to improve study processes? Select one of the following. (Q.16)

What benefits were achieved with your organization's implementation and use of the eTMF solution specified in question 12? Select all that apply. (Q.13)

Conclusion

There is industrywide recognition that unifying clinical processes and systems is necessary to address the growing need to improve the quality and speed of study execution, as trials become increasingly complex and specialized.

Clinical information and process silos are the primary issues for CROs, with the integration of multiple applications reported as the top challenge they face with clinical solutions. Many of the legacy systems in use today lack the functionality needed to enable true end-to-end processes, visibility, and collaboration. For this reason, CROs are increasingly looking to a modern, unified clinical model to tackle these challenges and enable faster, higher quality studies.

Unified systems and processes – There is universal agreement that all CROs need to move to a unified clinical model to remain competitive and most see significant benefits in doing so including faster study execution, cost savings, greater study quality, and visibility across the clinical lifecycle.

The need to modernize information systems – Consistent with sponsors, CROs report that challenges with legacy CTMS applications limit their ability to improve clinical operations. All CROs report their CTMS only partially supports key clinical operations processes, and deficiencies prompt the need for manual tracking and reporting. Conversely, adoption of newer, active eTMF applications continues to rise year-over-year, with CROs reporting several benefits including improved inspection readiness, better visibility, and study tracking.

Collaborative clinical ecosystem – The number of applications used by CROs increases proportionally to the number of trials managed. Many of these applications are built on legacy systems and manual processes and support discrete clinical functions, creating information and system silos and making collaboration difficult. While CROs have significantly reduced their email usage since 2014, email is still a prevalent method of collaboration. This puts information outside of controlled processes and makes information tracking and collaboration more complex.

Survey Methods

The survey consisted of 16 questions, many of which included sub-questions with response matrices. Survey questions were designed for individuals with knowledge of clinical operations processes and with partial or full responsibility for clinical operations within their organization. The survey was commissioned by Veeva Systems and conducted by Fierce Markets. Completion of the survey was voluntary, and a $10 donation was made to Doctors Without Borders for each valid completion of the full survey. All respondents were offered a summary of the survey results. No other compensation was offered or provided.

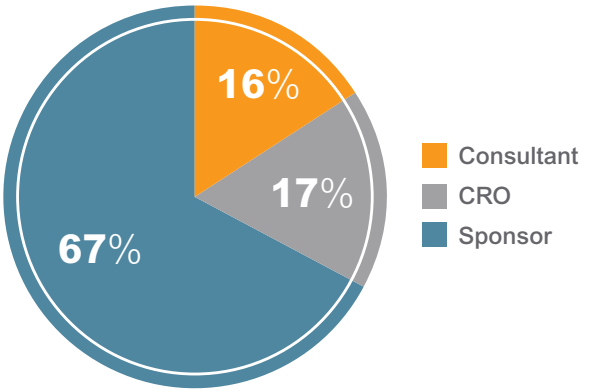
Survey Respondents

Of the approximately 300,000 individuals invited to take the survey, a total of 1,081 surveys were initiated, the majority of which were terminated based on a qualification question gauging the level of responsibility for clinical in their organization. More than 600 unverified responses were eliminated, yielding 300 qualified survey responses, 50 of which were from CROs.

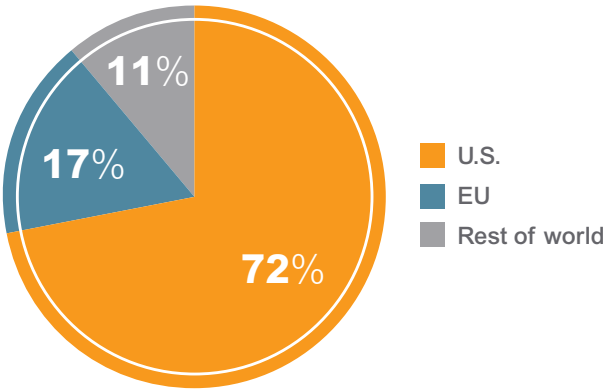
Survey Respondent Demographics

Base: Total respondents, N=300

Type of organization



Geographic location



Contact

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