White Paper

Connected Data Flow and Standards: A Data Management Approach

Combining processes, standards, technology and data flow accelerate clinical development with a functional service provider

Table of contents

Overview

Today's clinical research projects collect three times as much data as they did a decade ago[1], and electronic data capture accounts for very little of that. Making the most of the increasingly complex data and growing data volumes produces a challenge in Data Management, but it can be turned into an opportunity.
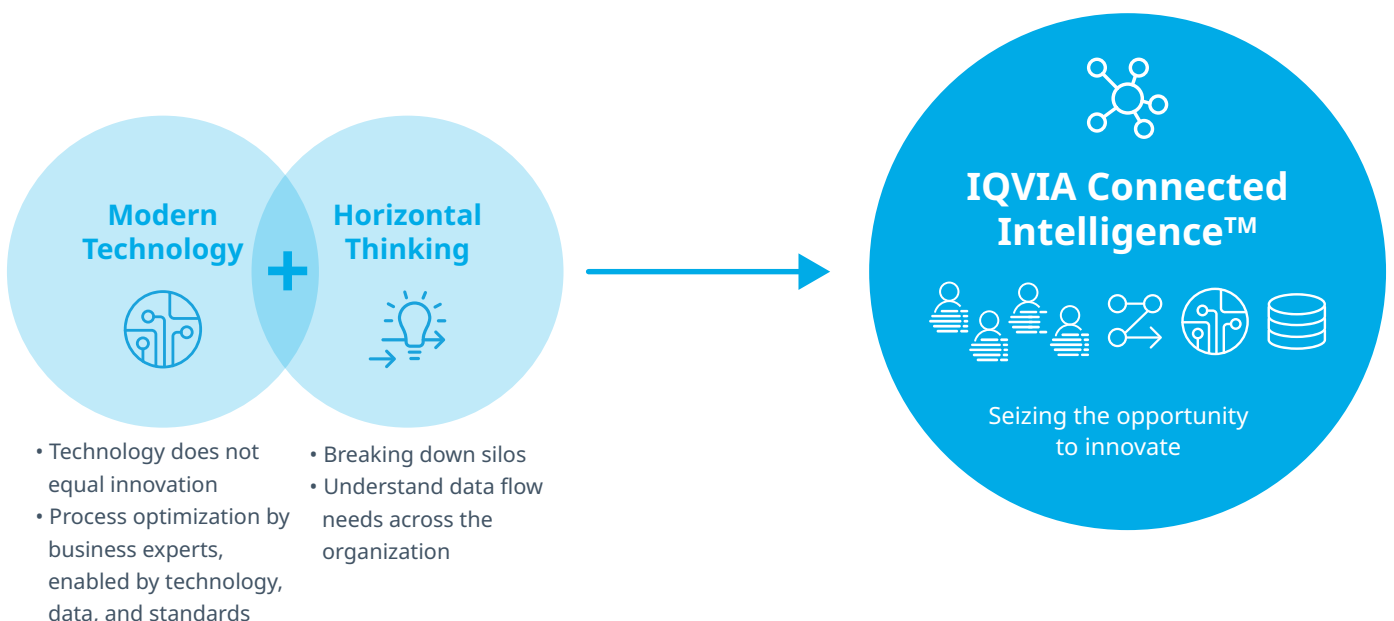
Addressing the Data Challenge

When the audience of a recent Applied Clinical Trials webcast[2] was asked how an organization addresses such dataflow challenges, about 40% of the participants said their organization did nothing or used only changes in processes, not new technology. Still, about 60% pointed out that their organizations have addressed this dataflow challenge by optimizing processes and applying new technology.

Although process optimization can provide some fast improvements, that can taper off quickly. Many new technologies can be applied to dataflow issues, but technology does not equal innovation. As shown

in **Figure 1**, modern technology and horizontal thinking must work together and fit an organization's ecosystem. That includes knowing how data flows across an organization.

IQVIA's Data Management experts work with a four-step innovation process to create connected data flow and standards: digitization, centralization, standardization and automation. Together, these steps address the data challenges, increase efficiency and optimize quality. To do that, experts implant human expertise into a technology-based platform through IQVIA's Connected Intelligence™. Let's explore each step.

Figure 1: Connected data flow and standards are an opportunity to innovate

Modern Technology
Horizontal Thinking

- Technology does not equal innovation
- Process optimization by business experts, enabled by technology, data, and standards

- Breaking down silos
- Understand data flow needs across the organization

IQVIA Connected Intelligence™

Seizing the opportunity to innovate

1. DIGITIZATION OF THE PROCESS

In most organizations, documents make up the foundation of legacy Data Management. As needed, employees share such documents, usually via email. That can make these documents hard to find by anyone other than the owner. Even when users can find these documents, the process is time-consuming. Plus, many legacy documents lack needed information, often due to a lack of guardrails that ensure the inclusion of certain expected content. Even worse, a series of users can modify documents in ways that can only be tracked through tedious, manual methods. Even in the best situation, this method is inefficient.

In considering the digitization of legacy documents, an organization faces many questions. Will it digitize all or some of its documents? How will digitization account for an organization's workflow of processes and data?
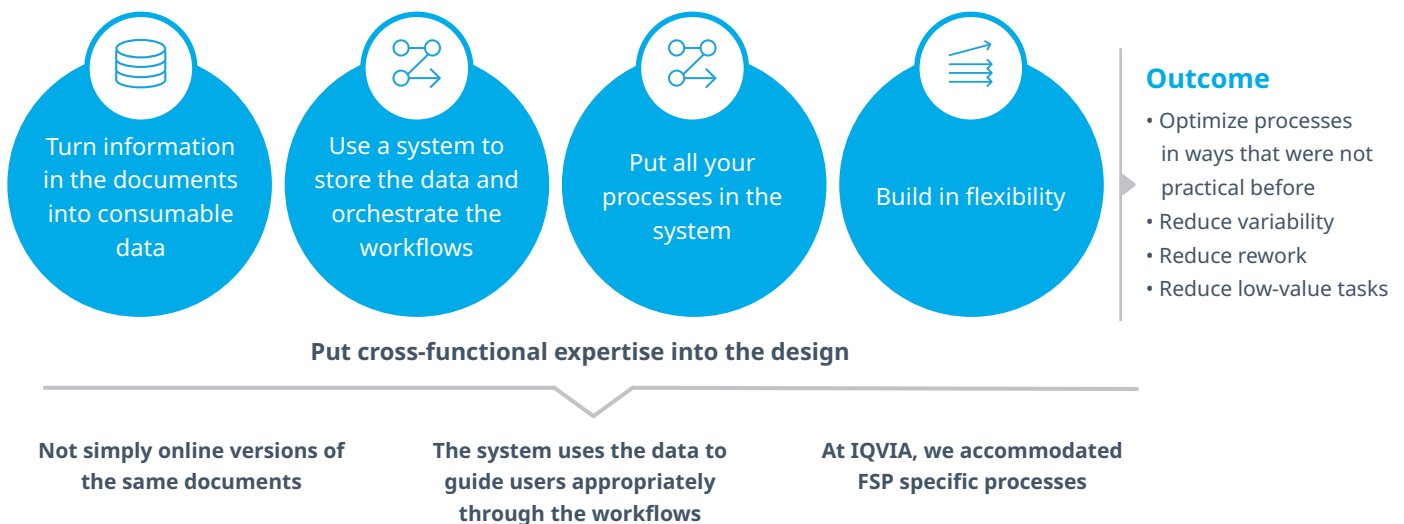
Figure 2 provides an overview of IQVIA's digitization process. In brief, this process turns document-based

Many legacy documents lack needed information, often due to a lack of guardrails that ensure the inclusion of certain expected content

information into usable data. The stored data can be used to efficiently control an organization's overall workflow. This system even walks users through the workflow as needed, which keeps processes consistent without any human intervention.

To make the most of such a system, an organization must digitize all its processes. Otherwise, manual intervention will still be required. If the digitization step reveals gaps in an organization's processes, they should be filled.

Figure 2: Step 1 – Digitize the process

Turn information in the documents into consumable data

Use a system to store the data and orchestrate the workflows

Put all your processes in the system

Build in flexibility

Outcome
- Optimize processes in ways that were not practical before
- Reduce variability
- Reduce rework
- Reduce low-value tasks

Put cross-functional expertise into the design

Not simply online versions of the same documents

The system uses the data to guide users appropriately through the workflows

At IQVIA, we accommodated FSP specific processes

In almost all systems, some flexibility is required. With the IQVIA system, customers can create flexibility where it's needed in Data Management.

Even with constructive process-digitization guidelines, an organization must dig deeper to make the most of this process. Instead of simply turning documents

into online mimics, think about how your organization has collected data and how that could be improved. Think of ways that the IQVIA Data Management system can help your organization improve its workflow and information use, all within guardrails that keep the processes consistent, high quality, and efficient.
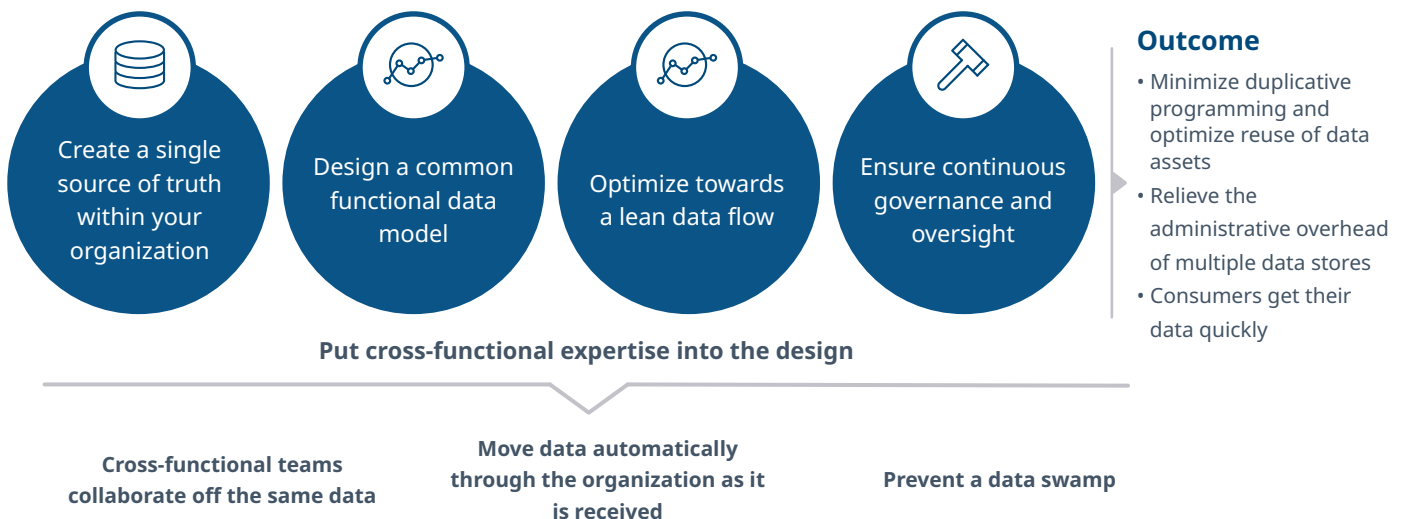
2. DATA CENTRALIZATION

Improving an organization's Data Management depends on first acknowledging some existing challenges, such as disparate data. Teams within an organization usually store data in their own places and in their own ways, as well as using team-centric processes. That makes it difficult to share data across teams in a company and to get an overall understanding of an organization's total collection of information. Such a lack of visibility puts the brakes on data flow.

This disparity in an organization's data raises some crucial questions. For example, how efficiently does data move through a company? If an organization uses artificial intelligence and machine learning, can those projects easily access the necessary data? Last, how do an organization's data and processes interact?

Think of ways that the IQVIA Data Management system can help your organization improve its workflow and information use, all within guardrails that keep the processes consistent, high quality, and efficient

Step two of the IQVIA system is centralizing data **Figure 3** The process starts with a data platform where an organization can create its single source of truth that can be shared among teams. To optimize these processes, IQVIA uses its cross-functional expertise to create a data environment that works for all teams. Also, the Data Management system must produce efficient data flow that works best for a specific organization.

Figure 3: Step 2- Centralize the data

Create a single source of truth within your organization

Design a common functional data model

Optimize towards a lean data flow

Ensure continuous governance and oversight

Put cross-functional expertise into the design

Cross-functional teams collaborate off the same data

Move data automatically through the organization as it is received

Prevent a data swamp

Outcome
- Minimize duplicative programming and optimize reuse of data assets
- Relieve the administrative overhead of multiple data stores
- Consumers get their data quickly

A sophisticated Data Management system also provides data governance. That is, data experts must continually monitor the data to ensure that customers can make the needed use of the information.

Simply putting data in one place won't meet the needs of most organizations, but a cross-functional design can optimize an organization's data flow in a customized way. The results of the latter approach optimize the reuse of data, reduce administrative costs of maintaining multiple data-storage methods, and the consumer can quickly access any of their data.
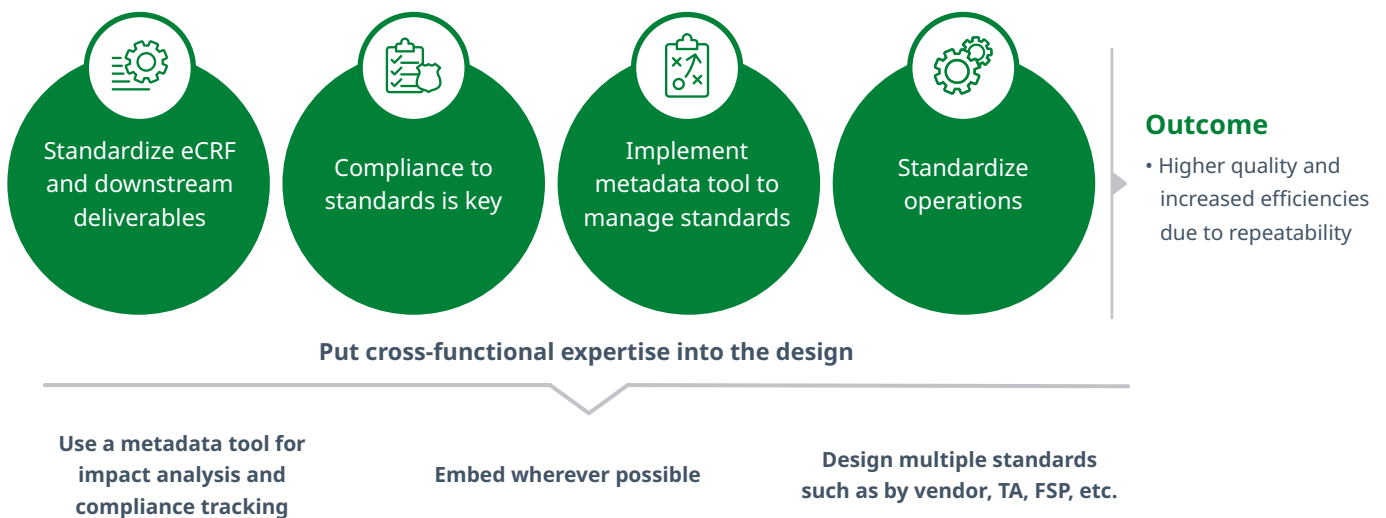
3. STANDARDIZATION

The third step in IQVIA's system is standardization. That's not a new concept in Data Management, but one in need of improvement. In the past, organizations, trying to create electronic data collection systems as quickly as possible, designed standard electronic case report forms (eCRFs) without strictly enforcing compliance.

Without connected end-to-end standards and a way to measure compliance, it's difficult to assess the impacts of allowed customizations on downstream deliverables, and that makes the management of changes difficult—often bordering on impossible.

To address these challenges, an organization should ask a series of questions. Are you complying with your eCRF standards? What have you standardized beyond your eCRFs? How do your standards work with your data and processes?

As shown in **Figure 4**, stopping at standardizing eCRFs is not enough. The eCRF standards must be connected with downstream deliverables such as edit checks, data review checks, study data tabulation model (SDTM) mappings, reports and so on. Most important, an organization's Data Management system must measure and track compliance with all relevant standards. The IQVIA system includes embedded standards such as those for specific therapeutic areas, vendors, functional service provider customers and more.

Figure 4: Step 3- Standardize

Standardize eCRF and downstream deliverables

Compliance to standards is key

Implement metadata tool to manage standards

Standardize operations

Outcome
• Higher quality and increased efficiencies due to repeatability

Put cross-functional expertise into the design

Use a metadata tool for impact analysis and compliance tracking

Embed wherever possible

Design multiple standards such as by vendor, TA, FSP, etc.

A metadata tool can manage and track end-to-end connected standards for all of the deliverables. As a result, any changes can be assessed for their impact on downstream outputs. The metadata tool can also track an organization's overall compliance.

Furthermore, IQVIA Data Management also standardized operational processes, then digitized them (step 1), ensuring consistency and compliance throughout a study's lifecycle.
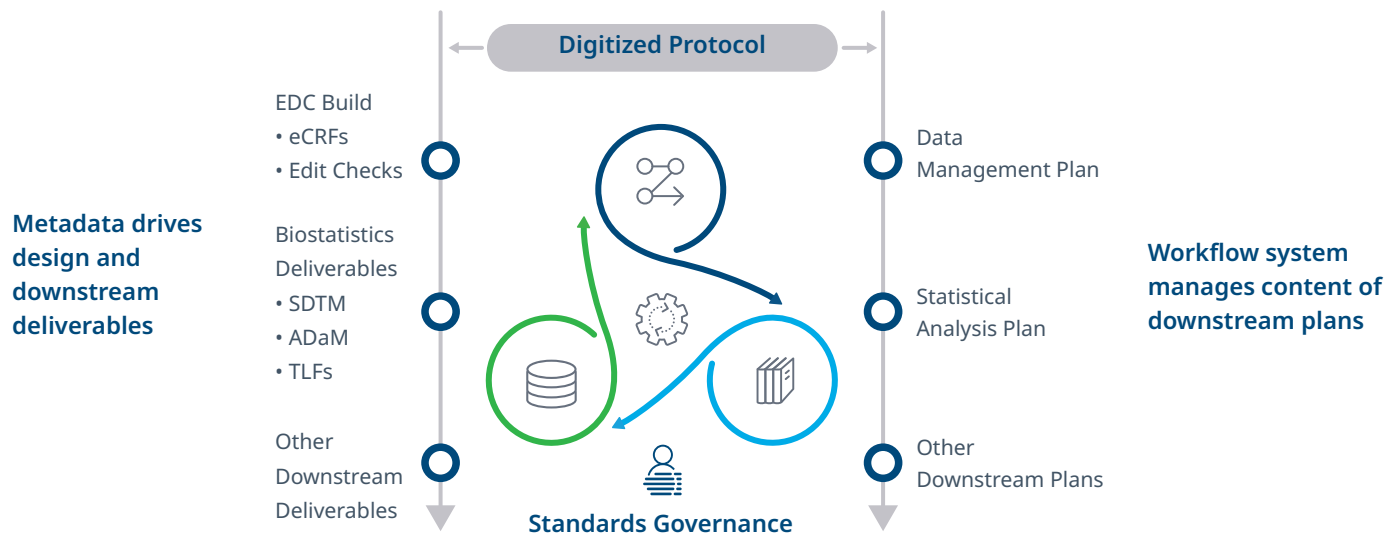
4. AUTOMATION

As organizations work with increasing volumes of data, everyone searches for improvements in efficiency. That means providing the highest quality deliverables in the least time and at the lowest cost. Automation provides a reliable way to meet those goals, but it's only possible with the repeatability that comes from centralization and standardization. So, with processes digitized, data centralized and standards embedded, an organization can move ahead with automation.

Figure 5 shows an automation example, which starts with a digitized protocol. The deliverables include eCRFs, edit checks, SDTM, analysis data models (ADaM), tables, listings and figures (TLFs), and deliverables that are downstream from all of these. Operational plans connect with particular deliverables. For example, the Data Management Plan corresponds with eCRFs and edit checks, and the Statistical Analysis Plan corresponds with SDTM, ADaM and TLFs.

Ultimately, such a Data Management solution can even allow for a push-button setup of a study

Figure 5: Step 4- Automate Study setup By applying automation, the IQVIA system guides a user through through study setup according to a set of rules. If there's a change in the protocol, the system determines the impact on the deliverables, and walks a user through the changes in the process. In brief, automation provides more benefits as an organization digitizes more information and applies more standards. The standards must be followed throughout the process, because a very small change at the start can expand as the process moves ahead. Ultimately, such a Data Management system can even allow for a push-button setup of a study.

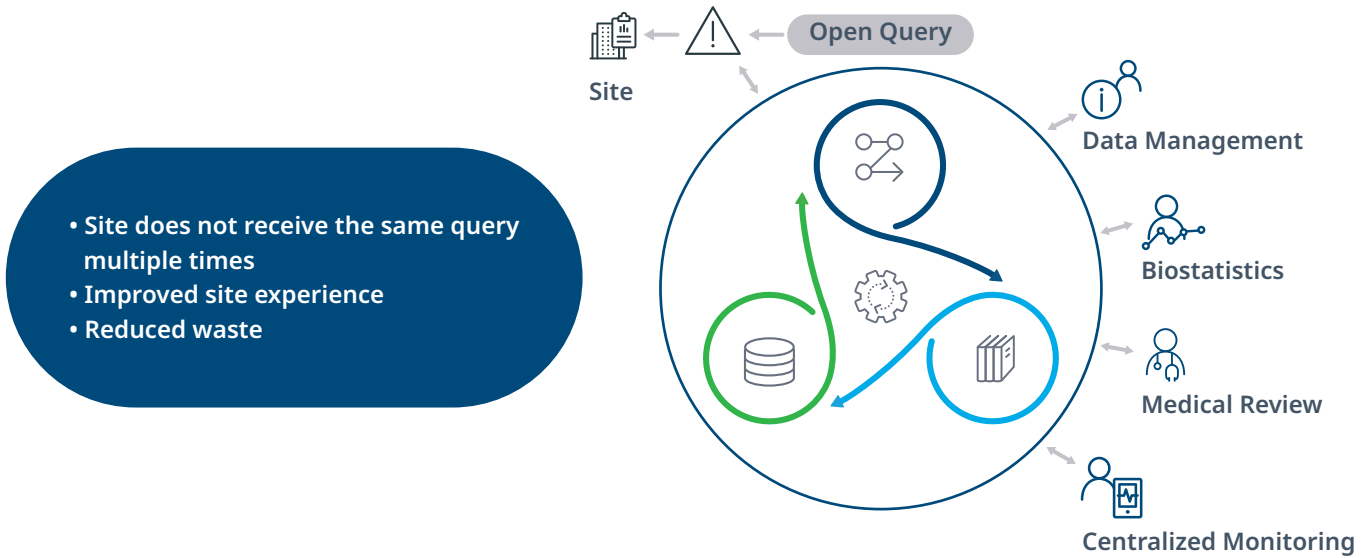**Figure 5: Step 4- Automate Study setup**

Furthermore, in an automated system, data flow must be carefully managed. The IQVIA Data Management system includes a real-time data cleaning solution. Here, data strategists make sure that the system is ready to receive data. The system runs defined data-cleaning algorithms and notifies users of new data

or issues that requires their attention. The key here is letting users focus on high-value activities, like managing issues, over low-value ones like executing programs and moving files manually.

Performing all of these steps within a unified system provides traceability and transparency. For instance, IQVIA's Data Review Module allows all team members on a project to examine the data and any project related issues, including ones raised by other team members **Figure 6**.

Figure 6 : IQVIA data review and issue management

- Site does not receive the same query multiple times
- Improved site experience
- Reduced waste

Open Query

Site

Data Management

Biostatistics

Medical Review

Centralized Monitoring

Conclusion

Combining technology and cross-functional expertise through IQVIA's Connected Intelligence™ allows customers to make the most of intelligent connections between processes, data and standards. That enhances the efficiency of healthcare projects and drives innovation. Ultimately, the improvements in efficiency accelerate the path to treating patients with improved therapies.

References

1. Tufts Center for the Study of Drug Development. "Rising Protocol Design Complexity Is Driving Rapid Growth in Clinical Trial Data Volume" Tufts CSDD Impact Report Jan/Feb 2021. https://csdd.tufts.edu/

2. Applied Clinical Trials-IQVIA webcast on "Connected Data Flow and Standards: A Data Management Approach," June 11, 2021

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Christina Lentz Larsen serves as an Associate Director in the Data Management Innovation team of IQVIA's Data Sciences, Safety and Regulatory division. In this role, Christina leads the standardization and simplification of data management processes to transform the business, providing insight and guidance into IQVIA's next-generation unified data and process platforms. She has over 20 years' experience in the industry, across programming, data management, statistics and risk-based monitoring, and has worked both domestically and internationally within the large pharma, CRO, and technology spaces. Christina graduated with a Bachelor of Arts degree in Mathematics, Cum Laude from Boston University.
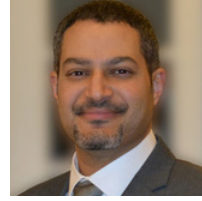
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John Gabra serves as an Associate Business Systems Director in the Data Management Innovation team of IQVIA's Data Sciences, Safety and Regulatory division. During the past 7 years in this role, John has developed numerous innovative technology solutions for the business. The latest was to help develop the next-generation unified data and process platforms. With an IQVIA Lean practitioner certification, John simultaneously drives process and technology improvements. Prior to this, John has worked for large pharma, clinical technology vendors, and clinical consulting, for a total of 18 years experience in the clinical trials industry. John holds a Master of Science joint-degree in Computational Biology from Rutgers University and the New Jersey Institute of Technology

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