12 Questions to Ask an eClinical
Software Vendor About Its Open API

By Blake Adams

Capabilities Now and in the Future

The clinical research landscape is changing…drastically. Clinical trials operate very differently than they did 10 or even five years ago. In particular, today's clinical trial requires robust eClinical systems across every function.

To realize the benefits of eClinical systems, research sites, sponsors and CROs must ensure that each system can integrate with other systems through open application programming interfaces (APIs), or, more simply, that they can "talk" to other systems now and in the future.

In theory, a single "all-in-one" system would eliminate the need for APIs, but how likely is it that an all-in-one system would be "best in class" across all applications now and in the future? How likely is it that an all-in-one system will really handle every need? In reality, an all-in-one system is likely to deliver sub-optimal performance in some areas and will still require an API for others. APIs let a research site, sponsor or CRO interconnect best-in-class systems across all functions.

An API is thus an essential requirement of any eClinical solution that claims to deliver optimal performance. Even if a closed system (one without an open API) is the best solution across every function for you today, how likely is it to be the best solution next year or in five years? APIs give you much more flexibility to upgrade your eClinical systems as your needs change or new systems emerge.

One advantage of an all-in-one system is that it can provide a consistent user interface across all functions. However, different functions might perform better with different user interfaces optimized to each particular function. In any case, even the most comprehensive all-in-one system will still likely need to talk to other systems in your organization and potentially with systems in other organizations.

Another advantage of an all-in-one system is that data need be entered only once. APIs address this issue by sharing such data with other systems automatically.

What is an API?

An API is a mechanism whereby one computer system lets other computer systems request it to perform certain actions in a reliable and secure manner. In a very simple example, System A might ask System B to tell it the number of patients in System B that have Type 2 diabetes. System B then responds with that number. In practice, communications across systems can be much more complex.

An "open" API is an API that system developers have made public for use by customers, vendors and others.

Examples of API use in clinical research include the following:

- An electronic medical records (EMR) system could submit data about patient visits to an eSource system.
- A clinical trial management system (CTMS) could verify that the site's billing system has not charged patients for study visits.

- A clinical trial management system (CTMS) could ask the EMR what medications a prospective study patient is taking.
- A clinical trial management system (CTMS) could report financial results to the site's financial system.
- An eRegulatory or eSource system could allow other systems, like the CTMS, to create or edit regulatory documents throughout the life of the study.
- A sponsor's eTMF system could pull new documents from a research site's eRegulatory system.
- A sponsor's EDC system could tell its financial system to pay a site. That system could initiate electronic payment to the site.
- A study startup package with all roles, assignments, permissions, and folder/binder structures built could deploy replicated structures in all eClinical platforms with one click.
- When someone signs onto one system, that user could be automatically signed onto other systems, as well.
- User messages in one system can be forwarded to other systems, such as notifications from the eRegulatory platform being routed to the CTMS.

As you can see from these examples, APIs can facilitate communications across organizations and between clinical research systems and clinical care systems. No all-in-one system will ever be that comprehensive.

Questions to Ask Vendors about their API

When you consider acquiring a new computer system, it is not enough to just ask whether that system has an API. You have to dig deeper by also asking the following questions:

1. Do you have an open API?

Does the vendor make its API open to customers, vendors and others? If it is only open to customers, you will have to make the connections between vendor systems yourself.

2. What functions does your API support?

The more comprehensive the API functions, the better you will able to integrate your systems.

3. How are your APIs secured?

APIs should be secured to prevent their use by unauthorized systems. What are the security measures, including the process of provisioning authorization keys or other mechanisms that allow connections from other systems? Have there been security breaches in the past?

4. Do you offer an SDK?

A software development kit (SDK) makes it easier to use an API with various programming languages.

5. What API documentation do you offer?

The complicated nature of technical integrations means the API your vendor provides should be well-documented.

6. Are there any limitations, such as on the number of API calls per day?

Vendors typically protect their APIs to avoid abuse, e.g., by limiting the number of calls per second to their API, known as "rate limiting." While rate limiting is a good practice, make sure it will not interfere with your legitimate use of the API.

7. Is your API metered?

Similar to rate-limiting, does the vendor charge for exceeding a specific number of calls to its API? Ideally, the answer is "no." Certainly, the cost should not be prohibitive.

8. What is your policy on API updates?

Vendors should not change their API without giving you adequate time and information to update your own software code. The tricky part is the vendor's policy on urgent API updates.

9. What is your API retirement policy?

Vendors typically expand their API based on customer requests and as their systems grow in functionality. At some point, obsolete API methods might be retired for new versions. You will want at least six months' notice to update your code.

10. Does your system have both inbound and outbound APIs?

This feature is probably the most overlooked question when evaluating APIs, and it's very important when you want to build complex workflows. A real-world example of inbound and outbound APIs in action is when a user uploads a document into your eRegulatory system. That system then uses an API to notify your CTMS of this action so the CTMS can trigger the next step of the workflow. Without an outbound API, your CTMS would have to constantly poll your eRegulatory system to see if a new document has been uploaded. This process is inefficient, consumes resources, and it is more challenging to implement.

11. Have you already integrated your system with any other systems?

If the vendor has already implemented an integration, you won't have to do it yourself. Alternatively, the vendor might be able to refer you to an existing customer that would consider sharing its integration code with you.

12. Does your system support any eClinical industry API standards?

As of the today, no such standards exist, but the MAGI eISF+eTMF Initiative is finalizing a standard reference model for site regulatory documents so sponsor eTMFs can communicate with site eRegBinders.
(See: https://www.magiworld.org/resources/journal/2293_ISF_Reference.pdf)

Conclusion

Technology evolves. The best solution today will not be the best solution tomorrow. APIs support maximum flexibility so you do not get locked into an inferior system architecture. Many of the biggest opportunities to automate workflow processes involve communications across different departments within an organization and across multiple organizations. Research sites, sponsors and CROs should thus design systems that support these complex workflow processes. Open APIs are an essential element of these systems.

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