



INTIENT CLINICAL MAE

VIDEO TRANSCRIPT

[00:00:04] Hello, thank you for your interest in the INTIENT Clinical Suites Managed Analytics Environment, or MAE. The MAE is a part of the INTIENT clinical study data solution, focused on preparing clinical trial data for regulatory submission. Let me show you how the MAE acts as Next-Generation Statistical Computing Environment, overcoming many of the limitations of traditional SEE's by providing a cloud native, multi-language environment to create and execute clinical programs. We begin by creating an analytics project.

[00:00:39] This can be done by adding a project to a registered study or by creating a new project and associating it to one or more registered studies. Once the project is created, it appears on the project list, which contains all projects that you have permission to access. The link on the right provides direct access to the analytics environment for the project, but all the functionality needed by a clinical programmer is available through the clinical UI. If we look at an existing project, you'll see that all the study information is associated with the project. We also have the ability to set up milestones. Think of these as deadlines for deliverables. To create a milestone, we choose a date and give the milestone a name. Let's say Interim Analysis 1. We can then assign specific deliverables to the milestones that will be tracked via business process management or BPM workflow. This tracking is designed to be flexible, allowing tracking to be done at different levels of granularity. So, for example, we can track the preparation of an individual domain data set. We can add an additional workflow to track a group of domains, let's say for a safety analysis, where we would then select multiple domains corresponding to those that we need to do the analysis. Let's say exposure, adverse events, labs. Or we can create a tracking workflow at the general project level, let's say ADaM Data Prep. Because these workflows are tied to BPM software, this also provides us with tasks that can be assigned to individuals or teams.

So, a clinical programmer can come to the tasks page and see at a glance all the work that they have to do. They can also view tasks assigned to others on the project, making it easy to see whether progress is being made on any work they are dependent upon. This greatly enhances the efficiency with which work can be assigned and tracked.

[00:02:44] Now, to actually do the programming work, we go back to the project details page where we have the ability to spin off workspaces for SAS and R programming languages. The ability to work in a multi-language environment is one of the key benefits of the MAE, and it is extensible by design, allowing additional tools and languages to be added based on an organization's needs. If we go ahead and open one of these workspaces, you'll see that we have true R studio SAS studio programming environments. Here's R studio and SAS studio. We can upload files, open programs, view data, run scripts and generate outputs, as in any other programming environment. Think of this as our interactive workspace where we develop the programs we need.

[00:03:32] The ability to spin up these environments on demand is another of the major benefits of the MAE and the INTIENT platform as a whole, being a cloud native application. We're not resource constrained, as in many traditional SEE's, built on fixed capacity hardware. This gives us the flexibility to handle newer forms of data that are frequently a challenge to process in older platforms because of the data size with the computing power needed. One other benefit is that committing changes to a central repository is built into the process of shutting down these on demand resources, meaning that almost no work is required on the part of the clinical programmer to reap the benefits of version control in their day to day work.



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[00:04:13] Now, when we're ready to generate outputs for regulatory submission, we need to execute our programs in a controlled fashion for compliance purposes. For this, we return to the clinical UI and go to the Run List screen. Here we can name our runs for easy tracking and execute specific programs is needed. This provides a record of executions for traceability and audit trail purposes. So, let's do a run called Interim Analysis 1. And we'll execute three programs, just as we saw we had in the environment. You can see that each program is recorded on the table here. Now because of the built-in version control, we have the ability to re-execute these programs at another, at any time using the exact same code, source data and software environment that was used originally. Providing an unparalleled level of reproducibility and eliminating the scramble that often accompanies the need to respond to a regulatory inquiry. Lastly, we have easy access to the logs for the run, as well as the results that were generated, making it simple to track, review and reconstruct work on demand. Based on what you've seen here, we hope you'll agree that the MAE represents a next generation capability for your clinical teams.

[00:05:35] The MAE is just one piece of the INTIENT Clinical Suite which helps our clients run more efficient, transparent clinical trials. An INTIENT Clinical is an integrated part of the INTIENT platform, a comprehensive, unique platform that enables insights and collaboration across life sciences and health care. If you're interested in hearing more details about the MAE, the INTIENT Clinical Suite or the INTIENT platform in general, we'll hope you'll reach out and arrange a demo.

Please visit our website at accenture.com/INTIENTClinical to learn more. Thank you.

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