

VIDEO TRANSCRIPT

INTIENT™ CLINICAL

The INTIENT platform enables insights and collaboration across life sciences and healthcare.

INTIENT's core capabilities include:

- a compliant and secure infrastructure,
- machine learning-ready data management tools,
- DevOps and testing tools, and
- common runtime.

INTIENT also includes specific capabilities across four product suites:

- Research
- Clinical
- Pharmacovigilance and
- Patient

The platform is powered by Google Cloud and supported by the INTIENT network partner ecosystem, giving access to independent software, services, hardware and content providers on Google Cloud's open architecture.

Google Cloud's innovative technology also enables secure, compliant application of AI and advanced analytics.

Let's have a closer look at INTIENT Clinical:

The INTIENT Clinical product suite provides solutions to meet the needs of clinical development teams, including a study data solution and an operational insights solution.

Our capabilities range from protocol authoring through regulatory submission, to investigating patient cohorts for trial planning and monitoring health and performance during trial execution.

Today, we'll focus on the Clinical Study Data Solution which is made up of five modules.

Each module can be used independently, but together they are designed to deliver maximum value.

The Study Data Engine module enables more efficient creation of regulatory deliverables. Compliant SDTM and ADaM datasets as well as TFLs can be created and automatically tested within the module.

Let's dive in and see what it's like to prepare clinical data using the Study Data Engine.

Emma is a Clinical Data Analyst assigned to transform clinical study data into SDTM format.

She starts by logging in and selecting the Produce SDTM option.

She registers the new study in the system, and enters her study's details.

On the study info page, she uploads her configuration file, which defines the mapping instructions.

To ensure all source-to-target mappings are correct and working, she now triggers a mapping verification.

The verification report shows the results as passes or fails. All mappings have succeeded, so

Emma is now ready to run her mappings against the actual source data.

She loads her source data, selects the SDTM domains she wants to generate, as well as her configuration file, and clicks on "Run Conversion."

The system now performs the defined source-to-target mappings, and provides a summary report of the run.

From here, Emma can view profile reports on the SDTM data, as well as the tables that were created.

She can also access the Pinnacle 21 report, to make sure the final data are compliant with the SDTM data model.

Emma is now ready to create her final SDTM deliverables.

She marks the SDTM data as “downstream ready,” so the analysis team can pick up the data for their activities. Emma then clicks on the Generate SDTM Package icon.

After selecting the types of documents and formats she needs, the SDTM package is created by clicking a single button.

The system produces the package in a ready-to-use format for submissions, in proper eCTD format and file structure.

That’s it for Emma! She has transformed her study data in a few easy steps and without duplicate programming.

The SDTM-formatted data can now be used in the “Produce ADaM” module to prepare an ADaM dataset for the analysis team.

Any custom work needed on the dataset can be done in the “INTIENT Clinical Analytics” module.

It provides cloud-based dynamic compute capacity and multi-lingual support.

The Managed space provides traceability through data and code tracking, while the Exploratory space gives users large degrees of freedom for data science and simulations.

Working together, these modules provide a truly next-generation capability to power your clinical teams.

This demonstrates only a small portion of the value that INTIENT Clinical delivers each and every day.

INTIENT Clinical helps our clients run better, more transparent clinical trials by enabling efficient aggregation of data, performing data analyses and driving study and operational insights.

And INTIENT Clinical is an integral product suite within the INTIENT platform, a comprehensive, unique platform that enables insights and collaboration across life sciences and healthcare.

Please visit our website at [Accenture.com/INTIENTClinical](https://www.accenture.com/INTIENTClinical) to learn more.