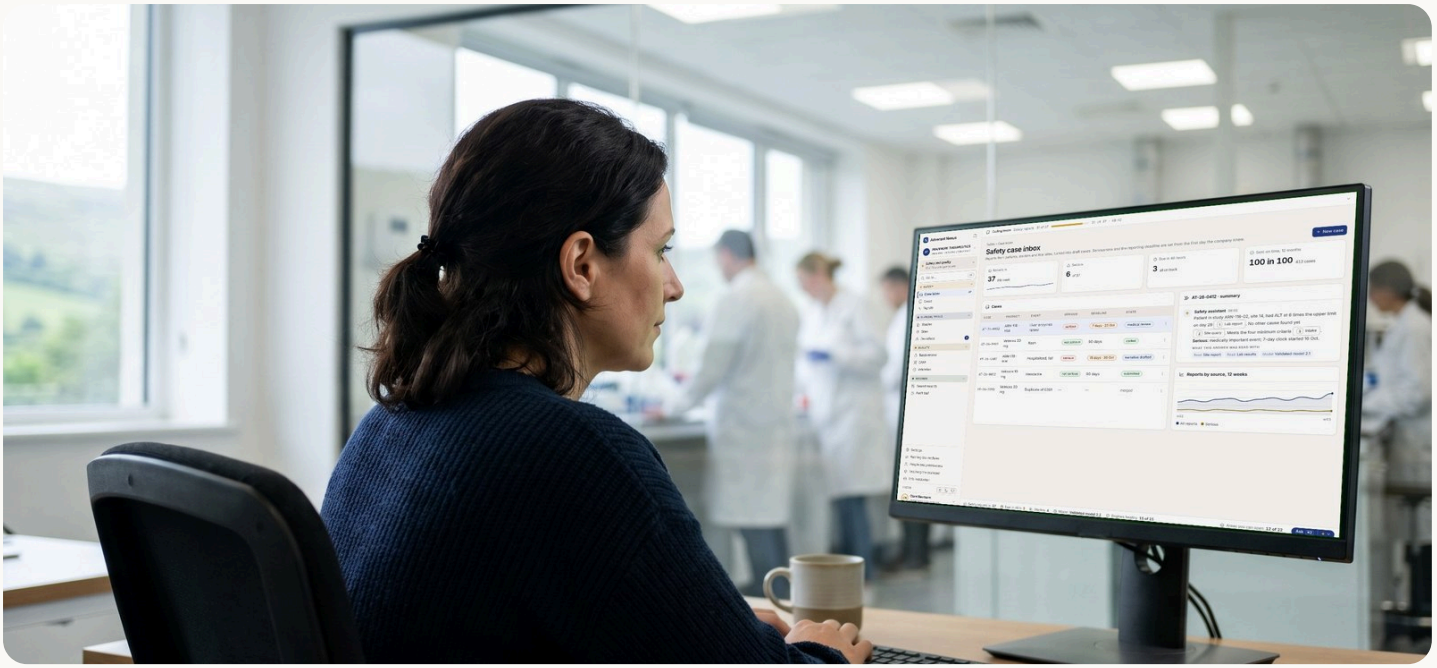
ADVERANT NEXUS · LIFE SCIENCES PACK

AI for trials, safety and quality. Ready for your validation.

The life sciences pack brings safety cases, trials and quality records to Nexus. AI reads case reports, drafts narratives and spots deviations, with every source shown. Qualified people decide. Every record is sealed, with the audit trail inspectors expect.



Safety cases. Seriousness and deadlines set from the day the company knew. Sample data.

Less transcribing. More judgement.

Safety cases processed with sources

Reports from email, calls and literature are read, coded and checked for duplicates. Every fact links back to where it came from.

Deviations caught early

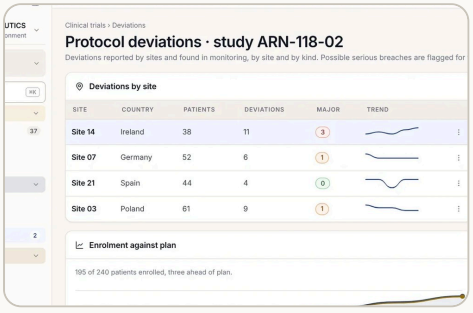
Trial and batch records are checked as they arrive. Possible serious breaches are flagged with the seven-day clock already running.

Validation you can hand to an inspector

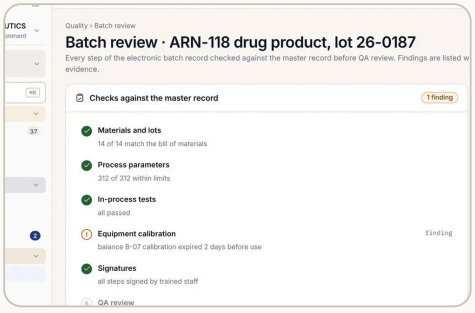
Each AI use keeps its intended use, test results and limits, alongside an audit trail that cannot be quietly changed.

Screens for each desk

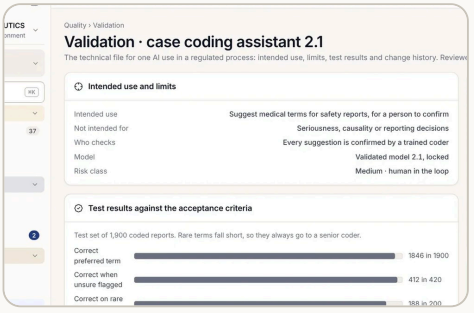
Sample screens with a made-up pharma company



Trial deviations. Deviations by site and kind, with a possible serious breach flagged.



Batch review. Every step checked against the master record before QA.



Validation. Intended use, limits, tests and change history for one AI use.

The life sciences pack
Every screen and rule
adverant.ai/industries/life-sciences

Watch the film
The 10-minute tour
youtu.be/eohd-5gDap4

Don Scott
don@adverant.ai

Adverant Limited · Registered in Ireland, company number 826944 · Venture Hub, 136 Capel Street, Dublin.

Who uses it

One pack, with a view for each role

Case processor

New safety reports, extracted facts, duplicate checks and narratives to finish.

Medical reviewer

Serious cases, causality to assess and the evidence behind each fact.

Clinical operations

Deviations by site, possible serious breaches and their deadlines.

Quality assurance and Qualified Person

Batch records, findings and what stands between a batch and release.

Validation lead

Each AI use, its tests, its limits and every change made to it.

How it works: from first report to a sealed assessment.

01

Receive

Reports arrive by email, phone, partner feeds and literature.

02

Read

AI extracts the facts, codes the terms and looks for duplicates, with sources.

03

Assess

A medical reviewer judges seriousness and causality.

04

Seal

The assessment, the narrative and the submission are sealed.

WHAT IS SEALED

Every assessment, with its audit trail.

When a reviewer signs off a case or QA closes a finding, the pack seals the record with everything it relied on.

Anyone can check a sealed decision offline with a free verifier, without an account with us.

THE RULES YOU ANSWER TO

- **EU GMP Annex 11** · EudraLex Volume 4
  Computerised systems: validation, audit trails and e-signatures
- **EU GMP Annex 22, draft** · Consultation draft, July 2025
  AI in GMP: intended use, test data and explainability
- **Clinical Trials Regulation** · Regulation (EU) No 536/2014
  Trial conduct, transparency and serious breach notice
- **ICH E6(R3)** · Good clinical practice
  Risk-based quality and data integrity, in effect from 23 July 2025
- **Pharmacovigilance** · Implementing Regulation (EU) No 520/2012
  Pharmacovigilance systems and their quality
- **MDR and IVDR** · Regulations (EU) 2017/745 and 2017/746
  Software that is a medical or diagnostic device

Run it where your quality system needs it.

Run the pack in our EU cloud or in your own data centre. Sites with strict controls can run offline.



Our EU cloud
Hosted in Europe



Your data centre
Or your own cloud account



The appliance
A box in your own rack



Fully offline
No internet connection

WHY ADVERANT

Nexus is one platform for every industry: the life sciences pack adds the words, workflows and rules, and the platform brings permissions, AI agents with limits, a budget for every model and a sealed record of every decision. Nine patent applications are pending in Ireland on how AI agents get authority, stay within it and have what they do recorded.

Don Scott, Founder and CEO, architect of Nexus. **Donal Hanafin**, Co-founder, two decades building products for regulated financial services.

HOW TO START

Pick one team and one job, such as triaging safety cases. We connect your systems, switch on the pack, and you see it working on your own cases. We can start on a copy of past records, so nothing live is touched until you are happy.

Show me with my own work
Don Scott, Founder and CEO · don@adverant.ai

The life sciences pack, in detail
adverant.ai/industries/life-sciences

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