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GI learning, personalised

Summary

Teaming up with pharma? Re-use of pre-clinical and clinical trial data - Clinical and pharmaceutical perspective

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Mechanisms & Personalised Medicine

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An experienced IBD investigator outlines pathways for academic researchers to advance personalised medicine, from registries and investigator-initiated trials through industry collaborations and data-sharing platforms, highlighting successes, failures, and practical barriers.

KEY POINTS

- The speaker described a spectrum of research approaches increasing in complexity: case series and registries, investigator-initiated trials, industry collaborations, shared datasets, and multi-partner consortia, each with distinct regulatory and funding challenges.
- The Titrate trial comparing infliximab dose intensification versus standard dosing in severe ulcerative colitis initially showed no difference, but when sigmoidoscopy videos were reanalyzed by artificial intelligence rather than expert review, personalised dosing appeared almost twice as effective—the first demonstration of AI-driven endoscopy interpretation altering trial outcomes, according to the speaker.
- Two large biomarker validation trials in Crohn's disease—Profile (transcriptomic) and the ongoing Omicron trial (epigenetic)—illustrate the difficulty and high risk of prospectively validating predictive biomarkers, with Profile failing to show clinical utility despite infliximab's known efficacy.
- Intestinal ultrasound is increasingly used in IBD trials because bowel wall thickness changes rapidly with treatment, more frequent assessments are feasible than with endoscopy, and patients prefer it; the speaker reported that an ultrasound-based appendiceal profile predicted appendectomy benefit in severe colitis (paper forthcoming in Lancet Gastroenterology).

- Investigator access to industry-generated datasets remains time-consuming, sometimes taking years, but platforms such as Vivli (Harvard) and YODA (Yale) now provide structured routes to over 7700 trials; umbrella contracts and AI contract review are emerging solutions to legal delays.
- In the speaker's view, pharma companies are open to investigator proposals if the work is original and aligns with their interests; collaboration works best when data ownership is shared across the consortium rather than held by a single partner.
