COD®
RESEARCH

COD NEWSLETTER

Mid-Year Roundup

Infinite Scientific Innovations

Whitepaper on Periodic Safety for Device Constituent Part

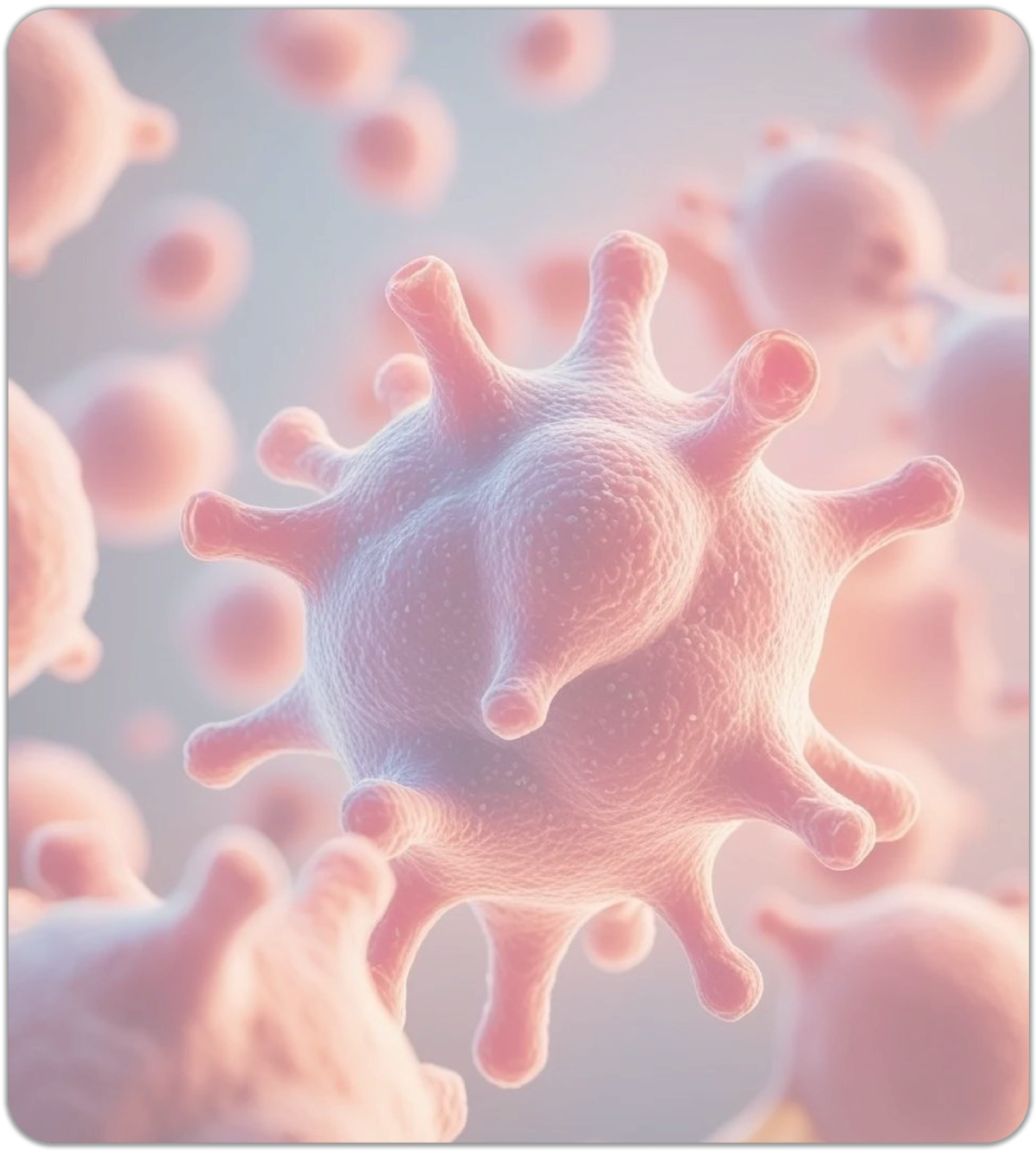
Stay ahead in the ever-changing USFDA landscape with our exclusive insights into periodic safety reports for device constituent parts. Discover how COD's key capabilities - Aggregate Reports, Risk Management, and Signal Management, enhance compliance and fortify safety strategies.

Read More

Case Study on Enhancing Access Through Patient Assistance Program

Explore how a tailored Patient Assistance Program (PAP), supported by a dedicated contact center, significantly improved access to neurological care. By focusing on access, adherence, and patient safety, the program demonstrated measurable success in helping patients better manage their Neurological condition.

Read More



Case Study on Complexities of a large-scale global Phase III Biosimilar Dermatology Trial

Discover our latest case study that delves into the complexities of a large-scale global Phase III Biosimilar Dermatology Trial. The study showcases how COD's strategies streamlined regulatory processes, enhanced site management, optimized patient selection and retention, and effectively managed investigational products (IP).

Read More

Case Study on Leveraging Agile Methodology: Building an FDA-Compliant REMS Contact Center

Discover how Agile methodology was instrumental in overcoming significant obstacles. This dynamic approach ensured the REMS program was not only responsive but also compliant with FDA requirements, meeting safety and operational standards effectively.

Read More

Other Recent Updates

- Successfully cleared a **PADE (PV) inspection** for a global client with zero observations or recommendations from FDA

- Completed a **600-patient global biosimilar trial** of XOLAIR® for CIU across the US, Jordan, and India with positive top-line results. COD managed the full lifecycle—from regulatory to CDISC—ahead of schedule and within budget, positioning the program for USFDA and EMA submission

- Successfully supported the implementation of a global intake tool (GIT) for case intake through tactical project management support, reinforcing our expertise in global pharmacovigilance operations and technology-enabled solutions

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