

2026 SOT Insights: FDA Regulatory Decision-Making in the Era of AI and NAM Bilingual (English/中文)

During the recently concluded SOT 2026, I experienced a week that was highly representative of my current work. On one hand, I attended one of the most important global conferences in toxicology; on the other, I participated in an FDA sponsor meeting in my role as an independent consultant. This combination of “conference + real-world engagement” provided a unique perspective on how scientific trends are translated into regulatory decision-making.



As an independent consultant focused on Regulatory Toxicology and Risk Assessment, my work primarily supports biotech, pharmaceutical, and chemical companies. I help teams anticipate potential regulatory risks from the early design stage, with the goal of reducing FDA questions and avoiding delays before IND/NDA submissions. Participating in an FDA sponsor meeting during SOT further reflects the core of my work, engaging directly in regulatory interactions and translating them into actionable strategies.

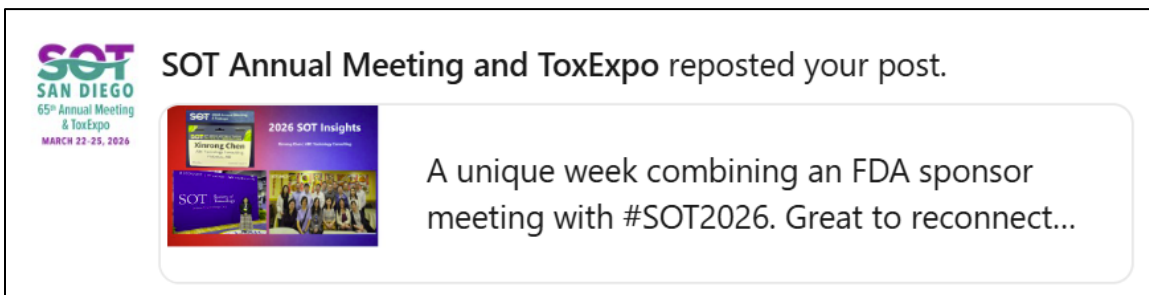
At SOT 2026, AI and NAM (New Approach Methodologies) were undoubtedly among the most prominent topics. However, the more critical question is not the technologies themselves, but how they can be appropriately integrated within existing regulatory frameworks. This is where the true value of data integration lies—bringing together NAM data, animal study results, and regulatory requirements into a cohesive evidence package that is acceptable to the FDA.

That said, discussions at the meeting also highlighted some important realities. While AI and NAM are widely discussed, many of the active contributors in this space still come from academia, research institutions, and data-limited sectors such as consumer products, chemicals, and risk assessment. In contrast, in drug development settings—where regulatory expectations are more stringent—the practical implementation of these approaches is still evolving.

From an industry perspective, NAM and AI have not yet become the primary revenue drivers for most assay development or testing service companies. Traditional assays continue to dominate. This reflects a broader reality: there is still a gap between technological advancement, regulatory acceptance, and commercial adoption.

One concept emphasized repeatedly in the [2026 FDA NAM guidance](#) is “context of use.” This is critical in practice. The same NAM dataset can have very different regulatory values depending on how it is used. Only with a clearly defined context of use can NAM meaningfully support risk assessment and decision-making.

On a personal note, I was particularly encouraged to see that my SOT summary shared on LinkedIn was reposted by the official SOT account. This serves not only as recognition, but also as a form of social proof—indicating that my perspectives resonate with broader discussions in the field.



From scientific discussions at SOT, to direct interactions in FDA sponsor meetings, and ultimately to strategy development in real projects, I am increasingly convinced that the most valuable work lies in connecting science, regulation, and decision-making.

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Open to discussions and collaborations.

If you are advancing an IND/NDA/BLA program or facing key decisions in toxicology, regulatory strategy, feel free to reach out:

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2026 年 SOT 会议洞察: AI 与 NAM

热潮下的 FDA 监管决策 Bilingual

(中文/ English)

在刚刚结束的 SOT 2026 期间，我经历了一个对我而言非常有代表性的一周。一边参加全球毒理学领域的重要会议，一边以独立咨询顾问的身份参与 FDA sponsor meeting。这种“会议+实战”的交叉，让我更加清晰地看到科学趋势如何真正落地到监管决策中。



作为一名专注于 Regulatory Toxicology 和 Risk Assessment 的独立顾问，我的日常工作主要是支持 biotech、pharmaceutical 以及 chemical 公司，从前期设计角度预判潜在的监管风险，帮助企业在提交 IND/NDA 之前就减少 FDA 问题、避免延误。这次在 SOT 期间同步参与 FDA sponsor meeting，本身也反映了当前工作的核心——直接参与监管沟通，并将其转化为可执行的策略。

在 SOT 2026 上，AI 与 NAM (New Approach Methodologies) 无疑是最突出的热点之一。但更关键的问题并不在于技术本身，而在于：这些新方法如何在现有监管框架下被合理整

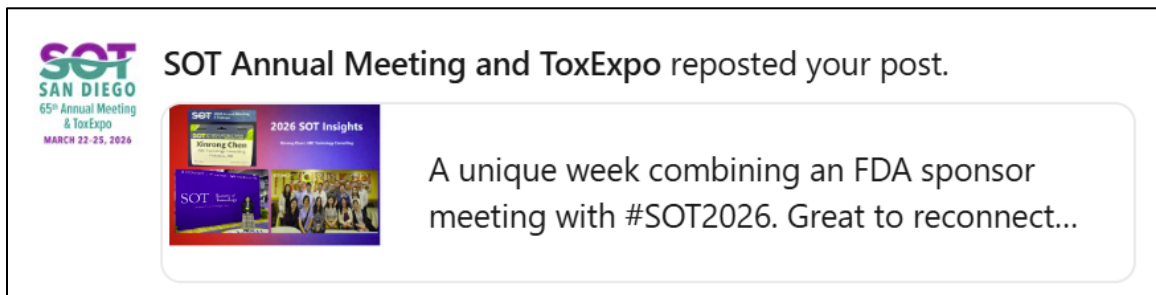
合与应用？这正是 data integration 的核心价值所在——将 NAM 数据、动物实验结果以及 regulatory requirements 有机结合，形成一个能够被 FDA 接受的整体证据链。

不过，从现场交流来看，也有一些值得冷静思考的现实。尽管 AI 和 NAM 被广泛讨论，但当前活跃在这一领域的多数发言者，仍主要来自科研机构、高校，以及数据相对不足的行业（如消费品、化学品与风险评估领域）。相比之下，在以药物研发为核心、对监管要求更为严格的场景中，这些新方法的实际落地仍在探索阶段。

同时，从产业角度看，NAM 和 AI 目前尚未成为多数实验或检测服务公司的主要收入来源，传统实验体系依然占据主导地位。这也反映出个现实：技术的发展与监管接受度、商业模式之间，仍然存在一定的时间差。

值得特别关注的是，近期 [2026 FDA NAM guidance](#) 中反复强调的“context of use”概念。这一点在实际项目中至关重要：同一项 NAM 数据，在不同的使用场景下，其监管价值是完全不同的。只有在清晰定义 context of use 的前提下，NAM 才能真正支持风险评估与决策。

另外，对我来说一个非常有意义的事情是：我在 LinkedIn 上发布的 SOT 总结，被 SOT 官方账号转发。这不仅是一种认可，也是一种 social proof——说明我的观察和观点，在一定程度上与行业的主流关注点产生了共鸣。



从 SOT 的科学讨论，到 FDA sponsor meeting 的实际沟通，再到项目中的策略制定，我越来越深刻地感受到：真正有价值的工作，是把科学、监管与决策连接起来。

欢迎交流与合作。

如果您正在推进 IND/NDA/BLA 项目，或在毒理、监管策略方面面临关键决策问题，欢迎联系讨论：

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