Dec 4, 2025

Clerky + Acorn

Invited sarah@acorncompliance.com Ian Nouvel ~~michael@acorncompliance.com~~

Attachments Clerky + Acorn

Meeting records Transcript

Summary

Ian Nouvel and Sarah Smith met to discuss the regulatory pathway for Ian's AI clinical guidance tool, which he demonstrated as a system that analyzes manually input clinical notes against a library of guidelines to suggest relevant information and modifications. Sarah advised Ian that the tool currently qualifies as a Class I medical device under UK regulation because it is "informing, not driving" clinical decisions, which allows for a quicker and more cost-effective route to market before expected legislative changes. Sarah outlined the necessary requirements for Class I regulatory compliance, including a quality system, a product technical file with an intended use statement, risk assessments, and a clinical evaluation report. Sarah also suggested "silent trials" as a method for Ian to gather clinical data and build an evidence base for the Class I classification.

Details

Notes Length: Standard

- **Introductions and Current Health Status** Ian Nouvel and Sarah Smith met, with Ian noting that Michael spoke highly of Sarah. Sarah apologized for a slow reply due to recent illness, a challenge Ian shared, mentioning their wife and children had also been unwell (00:00:00). Ian, a consultant obstetrician gynecologist with a background in computer programming, and Sarah, who works with Acorn and specializes in medical devices, regulatory compliance,

quality management, and data protection, exchanged introductions (00:00:44).

- **AI Clinical Guidance Tool Demonstration** Ian demonstrated the AI-powered website they had been developing for the past two years, which aims to provide clinical guidance (00:01:39). The tool allows users to input clinical notes, which it then analyzes to find relevant guidelines from a library of about 100 national and 200 local guidelines that Ian uploaded (00:02:36). Ian clarified that the system currently has no integration with patient records, requiring manual entry or copy-pasting of notes (00:03:34).
- **Functionality and Use Case** The tool suggests the most relevant guidelines and compares the input text against them, providing suggestions for text to add or modify based on the guidelines, such as the Rotterdam consensus criteria (00:04:34). Ian developed this tool to manage the increasing complexity in medicine and the high expectation for quick, high-quality consults, aligning with the NHS initiative "get it right first time" (00:07:34). The aim is to close the gap on failures to adhere to guidelines, which have been a factor in poor outcomes, especially in maternity (00:08:44).
- **Regulatory Classification and Market Strategy** Ian's ambition is to restrict the scope of the device to the maternity specialty in the UK initially to prove its value in a pilot and garner funding. Sarah advised on the current UK medical device regulations, noting that software often defaults to Class I classification unless it enters the diagnosis or active therapeutic space (00:09:56). They agreed the system is currently "informing, not driving" clinical decisions, justifying a Class I classification (00:10:59). Sarah noted that self-declaring as Class I allows for a quicker and more cost-effective route to market, which is beneficial before expected legislative changes in the next couple of years will likely raise the classification of such software to a minimum of 2A (00:13:05).
- **Class I Regulatory Requirements and Documentation** Sarah outlined the mandatory requirements for a Class I medical device in the UK, including having a quality system (though not necessarily certified), a product technical file, and strong risk rationale. Required documents for the technical file include the intended use statement, essential requirements checklist, risk assessments (which can align with NHS standards like DCB0129), testing data, and a clinical evaluation report (00:14:04). Sarah clarified that documentation can be kept electronically, potentially using platforms like Confluence or Google Workspace, and does not need to be submitted to the MHRA, except for registering and uploading the Declaration of Conformity (00:16:05).

- **Documentation Support and Accuracy Claims** Sarah mentioned that Acorn is developing functionality within their "squirrel" platform to help companies build their own technical documentation, empowering them to manage this internally (00:17:09). Regarding the required accuracy of the AI model, Sarah stated that the MHRA does not have a set benchmark percentage. Instead, manufacturers must make a quantifiable claim about the device's accuracy and provide supporting data (00:20:13). Ian noted that real-world data would be necessary to claim improvement in care (00:22:20).
- **Gathering Data and Path to Market** Sarah suggested looking into "silent trials," a concept used for collecting clinical data with friendly clinicians using non-patient data or preliminary user feedback, as a way to validate content and build an evidence base for the Class I classification (00:22:20). Ian proposed a modest initial claim, such as reducing the cognitive burden on the clinician, to facilitate market entry (00:24:24). Ian expressed the need for funding to hire team members and asked Sarah about the regulatory path timeline and cost (00:25:28) (00:27:33). Sarah estimated the process could take between four and eight weeks, with testing being the most common blocker (00:28:24). Ian plans to finalize the product and conduct some testing, including silent trials, to accelerate the process (00:29:16).
- **Next Steps and Resource Sharing** Sarah confirmed that she would speak to Michael to provide a proposal for the cost of Acorn's services (00:27:33) (00:30:03). Sarah will send Ian links to user-friendly guidance on the medical device regulations, information on silent trials, and examples of how user needs map to requirements and test protocols to help Ian prepare the necessary documentation (00:29:16) (00:30:03).

Suggested next steps

- [ ] Sarah Smith will ask Michael to send Ian Nouvel a cost estimate for Acorn's services related to the regulatory strategy.
- [ ] Sarah Smith will send Ian Nouvel some links to trusted sources that provide a more user-friendly version of the medical device regulation, along with guidance on silent trials and examples of a user need, a user requirement, a software requirement, and a test protocol.
- [ ] Ian Nouvel will finalize the product and set up possible silent trials with doctors to gather testing data.