NFTHD #44: Clinical Trial data – to share or not to share?

In this Note from the Help Desk, we answer a question about the appropriateness of sharing results of clinical trial data on pipeline products or new indications; largely whether it is considered promotion, and if not, how can it be communicated ethically and compliantly?

Our general advice is that sharing efficacy data from trials, along with certain results, can be deemed as promotional. As soon as we start talking about trial results and efficacy data, it becomes difficult to not to draw conclusions … and if those conclusions are favourable, and reflect favourably on the product, it can run a high risk of being deemed promotion. One of the tenets of scientific exchange is that any information provided on unregistered products or non-approved indications cannot be promotional, or it would contravene the Therapeutic Goods Act and the Code. It's a high-risk situation, and if in doubt, best not.

However, there are scenarios where communicating information about clinical trials can be done – the Code does not rule this out. Major factors to consider when deciding whether to communicate trial information is what it is communicated, how is it communicated and by whom. Communicating the results including efficacy data could "convey the positive attributes of a product". The Code's definition of promotional includes "statements concerning efficacy, rate of adverse effects or other cautionary aspects of the product and comparative information." To avoid the risk of promotion, you would need to avoid any statements concerning efficacy, and stick to communicating trial information such as Phase of the trial, subject inclusion and exclusion criteria, dosage being evaluated, comparators (if applicable), duration of the trial, randomisation, or outcome measures (but not the outcome results).

Context is key. One needs to consider the scenario fully: how wide is the audience, is it proactive or reactive exchange, what involvement does the company have, and is the content promotional? All of these factors combine to create an overall context and are likely to be considered if tested within a complaint.

So, what can we do to help ensure any trial results data are not communicated during scientific exchange and is not understood or perceived as promotional? As a starter, employing an independent steering committee is a sound and recognised mechanism to create distance between the commercial side and the medical/science side of your company activity. Whilst it doesn't negate your responsibilities under the Code, it creates independence. However we would also caution that any independent speakers be briefed comprehensively, and this is also documented.
So … communicating trial information can be done, but will need effective checks and balances put in place, a good degree of internal scrutiny, a controlled audience, and an understanding of the risks involved. Section 7 of the Code is the place to go for scientific exchange.

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