

## **Data and Safety Monitoring Board and the *Ratio Decidendi* of the Trial**

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### **Abstract**

Current decision-making by a Data and Safety Monitoring Board (DSMB) regarding clinical trial conduct is intricate, largely limited by cases and rules, and essentially secretive. Decision-making by court of law, by contrast, although also intricate and largely constrained by cases and rules, is essentially public. In this paper, I argue by analogy that legal decision-making, which strives for a balance between competing demands of conservatism and innovation, supplies a good basis to the logic behind DSMB decision-making. Using the doctrine of precedents in legal reasoning as my central analog will lead us to an analogy for much more systematic documentation and transparency of decisions in clinical trials. My conclusion is twofold: every DSMB decision should articulate a clear general principle (a *ratio decidendi*) that gives reason for the decision; and all such decisions should be made public. I use reported DSMB experiences of the Women's Health Initiative Clinical Trials to illustrate my analogical argument.

### **Introduction**

Most clinical trials in the U.S. and Canada designed to assess the efficacy and safety of medical interventions require periodic assessment of evolving trial data. Such trials demand oversight by a Data and Safety Monitoring Board (DSMB). The two main mandates of the DSMB are to protect the safety of trial participants and the scientific credibility of trial results (Ellenberg et al. 2003). In order to meet these two mandates, the DSMB is guided by a trial monitoring plan (revised by the DSMB itself prior to any data collection) that includes rules such as stopping rules, which dictate when the trial might be stopped, continued, or modified given interim data. Despite consenting to the monitoring plan, the DSMB has sweeping discretion over whether or not it ought to follow its own agreed-upon rules during trial conduct. Given that the DSMB has an information monopoly during all interim analysis, also having sweeping discretion over the course of the trial precludes most meaningful oversight of its decision-making (Eckstein 2015). Decision-making discretion by the DSMB becomes particularly challenging given the added fact that most of its deliberations happen behind closed doors, routinely not reporting publicly its interim decision reasons and recommendations (Wittes 1993).<sup>1</sup>