

# Open Source Software in Pharmaceutical Research

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## **Abstract**

Open-Source statistical software is being used with increasing frequency for the analysis of pharmaceutical data, particularly in support of “omics” technologies within discovery. While it is relatively straightforward to employ open-source tools for basic research, software used in any regulatory context must meet more rigorous requirements for documentation, training, software life-cycle management, and technical support.

We will focus on R, a full-featured open-source statistical software package. We’ll briefly outline the benefits it provides, as seen from the perspective of a discovery statistician, show some example areas in which it may be used, and then discuss the documentation, training, and support required for this class of use.

Next we will discuss what is needed for organizations to be comfortable with employing open-source statistical software for regulatory use within clinical, safety, or manufacturing. We will then talk about how well or poorly R meets these requirements, highlighting current issues. Finally, we will discuss options for third-party commercial support for R, and evaluate how well they meet the requirements for use of R within both regulated and non-regulated contexts.