**Let’s T@lk Real**

The RWD SIG Survey Results

19th December 2022

Hi Fellow Statisticians, Hi Real World Data enthusiasts,

Welcome to the first **Let’s T@lk Real** blog! This corner is created to discuss Real World Data (RWD) topics coming from industry, academia and Health Authorities. This may include new guidelines, new methods and really any RWD related topics raised by you and the statistical community.

This first edition will present the results of our survey conducted during the 2022 PSI conference, held in June when attendees gathered in Gothenburg for the first in-person conference in two years. The aim of the survey was to gather information on the **current use of RWD** in the pharmaceutical industry along with areas where **RWD can have a bigger impact** and areas responders are **curious to learn more**.

A total of 54 completed surveys were returned with varying degrees of completeness. Most responders (n = 48, 85%) worked for pharmaceutical companies or CROs with less than 10% of their role focused on RWD (n = 32, 59%).

Although observational research has been around for some time, Real World Evidence (RWE) is seen as a hot topic with regulatory bodies and various societies focussing on methods and guidelines for how to use RWE to support decision-making. This trend is reflected in the survey as well, where most responders (n = 37, 69%) had less than 5 years’ experience with RWD. The PSI RWD SIG recognises this is a great moment to contribute to this trend through education, showcasing lessons learned and sharing examples of successful case studies.

Survey respondents had the most experience with RWD use for publications (n = 22, 41%), prospective cohort studies or registries (n = 21, 39%), and secondary database/retrospective studies (n = 21, 39%). This contrasts with the areas responders were interested in and yet not involved in – which were all related to how RWD links to clinical trials: support trial recruitment (n = 22, 41%), help design clinical trials (n = 21, 39%), and RWD as e-source for trial data (n = 21, 39%).

The most striking result from the survey was understanding the greatest need or opportunity for statisticians to get involved. These included: external control arms (n = 36, 67%), RWD use for safety (n = 36, 67%), RWD use for efficacy/effectiveness (n = 33, 61%), RWD use for health economics (n = 30, 56%), and RWD use for internal decision making (n = 30, 56%).

What is the greatest need/opportunity for statisticians to get involved?

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **N = 54** | **Very important** | **Somewhat important** | **A little important** | **Not relevant** | **missing** |
|  |
| **Support indication selection** | 33.3% | 25.9% | 7.4% | 1.9% | 31.5% |  |
| **Help design clinical trials** | 48.1% | 18.5% | 7.4% | 0.0% | 25.9% |  |
| **Support trial recruitment** | 16.7% | 35.2% | 18.5% | 0.0% | 29.6% |  |
| **RWD as e-source for trial data** | 31.5% | 25.9% | 11.1% | 1.9% | 29.6% |  |
| **External control arms** | 66.7% | 9.3% | 1.9% | 1.9% | 20.4% |  |
| **Secondary database / retrospective studies** | 46.3% | 25.9% | 5.6% | 0.0% | 22.2% |  |
| **Prospective cohort studies or registries** | 44.4% | 22.2% | 1.9% | 0.0% | 31.5% |  |
| **Pragmatic trials** | 31.5% | 16.7% | 14.8% | 1.9% | 35.2% |  |
| **RWD use for Regulators** | 51.9% | 14.8% | 5.6% | 0.0% | 27.8% |  |
| **RWD use for HTA** | 50.0% | 11.1% | 9.3% | 0.0% | 29.6% |  |
| **RWD use for publications** | 53.7% | 13.0% | 7.4% | 0.0% | 25.9% |  |
| **RWD use for safety** | 66.7% | 11.1% | 3.7% | 0.0% | 18.5% |  |
| **RWD use for efficacy/effectiveness** | 61.1% | 16.7% | 0.0% | 0.0% | 22.2% |  |
| **RWD use for health economics** | 55.6% | 14.8% | 5.6% | 0.0% | 24.1% |  |
| **RWD use for internal decision making** | 55.6% | 14.8% | 5.6% | 0.0% | 24.1% |  |

This survey shows there’s a clear direction for statisticians to shape and contribute to the RWE and regulatory landscape as well as support the collaboration between RWD and clinical trials. We hope you’ll join us as we look to turn these survey insights into opportunities to share RWD best practices, highlight methodology for RWD, and advocate for high-quality research using RWD!

Many thanks to those that participated in the survey, if you would like to contribute and share your thoughts with the PSI RWD SIG, the link to the survey can be found here (<https://forms.gle/kyhpuy6V8pEhpcak7>). Special thanks to Rachel Tham for kindly handling and summarising the responses of the survey.

Thanks for reading our first blog. Please reach out with any topic ideas. Till we **T@lk Real** again!

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