# MYTHS VS FACTS

## ABOUT PATIENT REGISTRIES

| MYTHS | FACTS |
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| We can collect as much data as possible and figure out what to do with it later. | Knowing what you want to do with the data is critical in the beginning. This will determine the type of registry platform you use and the information you will collect. |
| We should wait for a lot of data to be available before we analyse it. | It's important to start analysing data as soon as you start collecting it to be able to catch errors and fix them early on. |
| The more data we collect, the better our registry. | More data is not always better. In fact, asking for lots of information may fatigue participants and result in missing or incomplete data. A smaller dataset with only what is necessary is often far more useful. |
| Using validated instruments is always the best strategy. | While it's important to explore the availability of the validated instruments, if they have not been validated for your disease, they won't necessarily be the best approach. |
| Doctors and researchers are experts on patient registries. | Doctors and researchers are able to provide input into the type of clinical information that is important to collect as well as help interpret results, but they might not have the technical expertise to run a registry. Relevant backgrounds are data analysis, statistical programming and biostatistics. |
| We can combine our data with data from other registries. | Combining data can be very challenging unless registries collect data, including data structure, questions, and response options, in the same way. Combining data is time-consuming and requires special expertise, which can be expensive. Therefore, if you want to combine data, it's best to plan for it early on. |

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| Once we have data, researchers and industry will be very interested in it. | There's no guarantee that researchers or industry will be interested in the data. Researchers usually need funding in order to work on the data and even then, results may not be available for months or years. Industry may be looking for data that is very high quality or supports a particular drug application. |
| Regulatory agencies (the FDA, EMA) are always interested in patient registry data. | There are multiple factors and requirements that may influence regulatory agencies' interest in your data. In the event that a regulatory agency does want to see your data, the best strategy is to have it the best quality possible. |
| Our data is protected by HIPAA. | HIPAA only applies to "covered entities", which includes healthcare providers, health plans and healthcare clearing houses. Most patient registry vendors and patient foundations don't fall into these categories, and therefore HIPAA doesn't apply to their data. |
| If I do everything right, my data will be highly valuable from a clinical perspective. | Besides the technical aspect of data quality, data quality is determined by the accuracy of self-reported data entry and the appropriateness of the questions asked. Both patient-reported and medical records data have limitations. |
| Patients own their data. | There's no clear definition on what "own data" means. Sometimes, patients can consent to how they want their data to be used and can withdraw from participation if they would like. However, the data that has already been extracted from the database may continue to exist. Better definitions of data ownership and clarity on data usage are necessary. |
| The more expensive the registry platform, the higher the quality. | Data quality depends on many factors, such as availability of a data dictionary, use of data standards, creating optimal surveys and doing data analysis, which are not necessarily dependent on the cost of the platform. |

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