

European infrastructure for translational medicine





- Academics often do not know much about the regulatory/approval/market authorization process
- Academics generally will be asking scientific advice for the first time
- Academic institutions rarely have resources to provide guidance on the scientific advice process
- Academics rarely have an understanding between clinical trials for research vs. clinical trials for registration

Potential additions/changes could include:

- Pre-meetings to learn what/how to ask scientific advice questions
- Scientific advice "navigators" who can translate between academic vs. regulatory language/expectations
- Advice services on how to put together scientific advice packages
- More web/in-person workshops to explain regulatory processes and the value of scientific advice