legal team may help navigate this process more efficiently. Third, the data sharing process can be lengthy, and FIT/ECs should be aware of expected timelines. This timeline may vary from project to project and may depend on the platform, but FIT/EC investigators should anticipate up to 1 year (11) prior to data analyses, a timeframe that may not be optimal for certain shorter fellowships. Fourth, as with most clinical research, financial and materials support is often needed for secondary use of shared data. Recent studies of data sharing have suggested that only one-half of proposals are specifically funded, and lack of funding and statistical support may be a factor in delaying analyses and publication (8). The NHLBI offers a R21 Exploratory/Developmental Research Grant ($150,000 over a 2-year period), which may be used to perform secondary analyses of studies included in their repository. Other funding avenues or support from a mentor may be required. Last, FIT/EC investigators should anticipate performing necessary statistical analyses themselves or including a biostatistician on the research team.

CONCLUSIONS

Individual patient-level data from cardiovascular clinical trials are expected to continue to be broadly shared and become accessible sooner after trial completion (1). Data sharing platforms provide researchers with access to participant-level data, which may broaden the scientific impact of collected data and bolster return of patient participation. Secondary use of shared data may be an important adjunctive resource for FIT/EC investigators to complement primary data generation. As such, FIT/EC investigators should familiarize themselves with available data sharing platforms, the process and practicalities of data acquisition, and the anticipated barriers to efficient utilization.

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RESPONSE: A Mentor's Perspective on Using Shared Research Data

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The increased availability of shared data from clinical research studies provides great opportunities for fellows-in-training to ask interesting research questions and get answers within 1 to 2 years, without having to organize a lengthy multicenter trial. McCarthy and Vaduganathan provide a useful roadmap to access these data, and I would like to offer some other points to consider before initiating a study.

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GET MENTORSHIP

I would strongly advise fellows-in-training to work with a faculty mentor to refine the research questions and plan the analyses of shared data. The model of fellows working with seasoned clinical researchers to learn best practices is sound, and training in research is best done "hands on," using individual patient data. A faculty mentor can help focus a research question into the sweet spot of being feasible, interesting, important, and novel. A faculty member also can help you apply the most appropriate methods, and can suggest additional collaborators who could enhance the project.

UNDERSTAND THE DATA

It is important for users of shared, secondary data to understand how the data were collected and what they mean before analyzing data collected by others. I have found it very useful to obtain copies of the data collection forms to see the precise wording of each item, what responses were allowed, how the data were coded, and how missing data were handled. It is helpful to write the variable names from the data dictionary next to the item on the data collection form to be very clear what each variable really means. It also can be very helpful to clarify the data collection processes with investigators from the original study to avoid misunderstandings and misinterpretation of secondary data. Before working on your own research question, it is a good practice to first exercise the data by doing some simple analyses, such as reproducing "Table 1" of baseline characteristics from the original study, to be sure you understand the data.

CONSULT A STATISTICIAN

The most interesting and important research questions require more than simple descriptive statistics. Multivariable statistical models can be tricky to apply and interpret, so it is a good practice to consult with an experienced biostatistician before embarking on an analysis of a secondary dataset. A statistical consultation (or collaboration) has the added bonus of enhancing your training in clinical research methods.

COMMUNICATE CLEARLY

Be open when writing up your findings, and follow the suggestions for publications based on shared data (1). Be sure to state clearly that your report is based on a shared dataset, explain how you obtained the data, and emphasize that the conclusions are yours, not those of the original study investigators. It is especially important to discuss why any of your findings and conclusions differ from those of the original study.

CONCLUSIONS

There are many important questions that can be addressed by analyzing secondary datasets shared by other researchers. The availability of these data can be a great opportunity for fellows-in-training to enhance their research skills, as well as to advance the field.

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