Regulatory & Contractual Compliance

All regulatory reviews and approvals must be obtained prior to initiating any related scientific activity (for example, IRB determination for human subject studies or IACUC approval for animal studies). No work related to the necessary determinations or approvals, including subject recruitment for human subject studies, may commence until the appropriate reviews have been completed and all required approvals are in place. Copies of regulatory approvals or other determinations should be forwarded to DATA managing director (itullett@med.umich.edu) for recordkeeping and reporting purposes.

DATA projects may not be duplicative or substantially similar to a project supported by other awards. DATA project statements, statements of work or protocols should be unique, distinct, and separate from other projects. Project teams should avoid commingling funds received through DATA with other awards to fund a single project. Overlap between projects could violate the applicable agreements or could impact rights to non-DATA intellectual property.

Intellectual Property (IP)

As an Industry-University Cooperative Research Center of the National Science Foundation (https://iucrc.nsf.gov/), DATA funding model includes government (federal) and private (industry) funds. Any intellectual property generated within a DATA project is subject to the applicable government rights and rights granted pursuant to DATA’s bylaws, including a right to a non-exclusive royalty-free license by DATA industry members. Innovation Partnerships (innovationpartnerships@umich.edu) is available to answer questions about the scope of this license. Work produced as part of a DATA project qualifies as a deliverable of a sponsored research agreement pursuant to U-M SPG 303.04.

If a project may involve the use of intellectual property developed outside of a DATA project, including IP of a project team member or IP provided by a third party (i.e., background IP), such intellectual property needs to be disclosed to U-M Innovation Partnerships (innovationpartnerships@umich.edu) before the project’s start, with a copy to DATA managing director (itullett@med.umich.edu). This is true even if the background IP is open-source. Please keep your disclosure(s) up to date through the project’s conduct, including any changes to already disclosed background IP (e.g., if you become aware of a new licensing agreement), additional background IP newly used in the project, etc.

Similarly, project teams are required to submit an invention report about any IP generated by a DATA award as soon as possible to U-M Innovation Partnerships, using the online reporting system at https://innovationpartnerships.umich.edu/submit-your-innovation/, with a copy to DATA managing director (itullett@med.umich.edu).

In the event a project team member has, or anticipates, a startup related to a DATA project, they should contact Innovation Partnerships (innovationpartnerships@umich.edu) in order to ensure that the IP rights in DATA are harmonious with the goals.

DATA industry partners may have a first right to sponsor a follow-on research project (a project directly building up on DATA-funded research) as a standard University sponsored project (i.e., outside of DATA).

Conflicts of Interest

As an NSF-funded IUCRC, DATA is required to follow the IUCRC program COI rules, including
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qualifying relationships between researchers involved in the Center and the Center’s industry partners. Please notify DATA managing director (itullett@med.umich.edu) promptly if you or any other member of the project team is, or becomes, the founder, president, a key officer, or a majority shareholder of a DATA industry partner. The list of DATA industry partners will be included in the proposal submission form, the award letter, project status reports, and is also available from DATA managing director.

Financial Administration

DATA awards include a ten percent (10%) indirect cost rate, which will be remitted to the project principal investigator’s administrative department. The funds will be disbursed using a project-specific shortcode. This funding is considered program income under federal award rules and is subject to the Uniform Guidance (https://orsp.umich.edu/uniform-guidance).

Award decisions are made on a year-by-year basis. Awarded funding needs to be spent before the award end date. Any remaining funds will be released back to DATA to support future programs. If a funded project is designed for multiple years, project teams are welcome to apply for continued funding during the following funding round.

Confidentiality

When communicating with DATA industry partners and DATA staff, project teams are requested to take special care to identify as confidential all confidential or proprietary information they convey. Confidential information may belong to U-M, a third party (such as research partners), or to project team members themselves, and it may be included in project proposals, presentations at IAB meetings, project progress reports and final reports to the IAB, or in background IP, among others. It could take the form of a paper copy, electronic communication, or a verbal statement. Researchers should keep in strict confidence any confidential information they receive due to their participation in DATA activities.

Unlike DATA affiliates, industry members are not contractually obligated to keep information about DATA projects confidential. Project teams are asked to notify DATA managing director (itullett@med.umich.edu) as soon as they identify a need to share confidential or proprietary information with an industry member, who will work with them and with the appropriate University central office on securing a non-disclosure agreement as necessary.

Reporting

Interim project status reports are due quarterly, with due dates as specified in the award letter. The final project report is due within thirty (30) days of a Center-funded project’s end date. These reports and any presentations related to the project’s progress will be distributed to DATA industry partners and may be shared with DATA’s governance and advisory committees.

Publication

It is DATA’s policy to make the results of DATA-funded research available for publication. Researchers involved in Center research are encouraged to present the methods and results of their project at symposia and professional meetings and publish the same, e.g., in journals, theses, or dissertations. Pursuant to the Center’s bylaws, DATA industry partners have thirty (30) days to review any publication or presentation containing the project methods or results prior to publication, and they have the right to request a delay in publication for a period not to exceed sixty (60) days from the date of submission of the manuscript or presentation for their review. Project teams are requested to share any manuscript or draft presentation with DATA managing director (itullett@med.umich.edu) at least seventy (70) days prior to the intended publication (presentation) so that they can be timely submitted to the Center’s industry partners.
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All peer-reviewed publications, including journal papers and juried conference proceedings or papers, will need to be deposited in the NSF Public Access Repository (NSF-PAR, https://par.nsf.gov/). Project teams should provide DATA staff promptly with a copy of any publication or presentation resulting from a DATA award (email to itullett@med.umich.edu). The following acknowledgement must be included in all publications or presentations:

“Research reported in this publication (presentation) was supported by the Center for Data-Driven Drug Development and Treatment Assessment (DATA), an industry-university cooperative research center partially supported by the National Science Foundation under the award number 2209546, and by DATA industry partners.”

Student Team Members

All students participating in DATA projects should be affiliated with the University of Michigan. Project teams are asked to have any undergraduate student(s) contact U-M Innovation Partnerships (innovationpartnerships@umich.edu) before they start working on the project so that they can discuss and timely execute any necessary assignments of intellectual property rights.