The YODA Project
Data Request Review Process

START
YODA Project receives Clinical Trial Data Request*

Request for CSR Summary only
Request sent to Data Partner to prepare
Request fulfilled END

YODA Project Performs Review
• Complete registration information and COI forms
• Proposal has scientific merit, including intention to use the data to inform science and public health

Scientific Merit is Unclear
Request has Clear Scientific Merit

To External Review

Data Partner Performs Due Diligence Assessment
• Assess the state of data requested (e.g., are data in an electronic format?)
• Partner considerations
• Informed consent considerations
• Estimate the resources needed to redact CSR(s) or de-identify IPD

YODA Project reviews Data Partner’s Due Diligence Assessment

Data are unable to be shared externally
YODA Project Does Not Approve

Data are able to be shared externally

Request Not Approved
- Decision and all materials posted - END

YODA Project Does Not Approve To External Review

Request made for:
• Redacted full CSRs
• De-Identified Individual Participant-Level Data (IPD)

*Inquiries regarding data availability can be submitted to the YODA Project prior to the submission of a full Data Request.
The YODA Project
Data Request Review Process

**External Review**
- YODA Project solicits two independent peer reviews to assess scientific merit, including public health importance
- Steering Committee Member(s) review

**External Review**
- YODA Project and at least one Steering Committee member discuss reviews

**Scientific Merit is Unclear**

**Request has Clear Scientific Merit**

**YODA Project Consolidates and Reviews:**
- YODA Project Review finding
- Data Partner’s Due Diligence Assessment
- External Review finding (if applicable)

**Data are able to be shared externally and request has scientific merit**

**Data are able to be shared externally but request does not have clear scientific merit**

**Request Fulfilled**
- Decision and all materials posted - END

**Data Partner redacts CSR(s) and/or de-identifies IPD**

**YODA Project Approves**

**YODA Project Does Not Approve**

**Request Not Approved**
- Decision and all materials posted - END