

NIH RADx-UP Data Categories for Ingestion by the CDCC and Deposit to the NIH RADx Data HubJune 2022

Data Category	Definition	Held by CDCC§	Send to NIH RADx DataHub ^{§§}
NIH RADx-UP Tier 1 CDEs*	RADx-UP CDEs inclusive of RADx executive CDEs. These CDEs are required from all projects in RADx-UP.**	Yes	Only de-identified
NIH RADx-UP Tier 2 CDEs*	RADx-UP defined CDEs. These CDEs are recommended, not required.	If the project captures the CDEs and shares them with the CDCC	Only de-identified
Mapped electronic health record (EHR) data to NIH RADx-UP Tier 1 CDEs that originated with participant consent	EHR data mapable to the NIH RADx-UP Tier 1 CDEs. These CDEs are required for projects extracting data from the EHR and who consented participants to extract their EHR data.	If the project or CDCC maps the CDEs and shares them with the CDCC	Only de-identified
Mapped electronic health record (EHR) data to NIH RADx-UP Tier 1 CDEs that originated WITHOUT participant consent and not classified as human subject research.	EHR data mapped to the NIH RADx-UP Tier 1 CDEs. These CDEs are required for projects extracting data from the EHR and who DID NOT consent participants to extract their EHR data. These EHR data are extracted by the projects in a manner (e.g. de-identified) which does not require individual participant consent and is classified as non-human subject research.	If the project maps the CDEs and shares them with the CDCC	Only de-identified
RADx-UP Harmonizable DDEs	Harmonizable Defined Data Elements. These are DDEs selected by projects for their project-specific use from the NLM CDE Repository, PhenX or DR2.	If the project shares them with the CDCC	Only de-identified
RADx-UP Non-harmonizable DDEs	Project-Defined Data Elements. These DDEs are created de novo by the projects and cannot be harmonized with other projects.	If the project shares them with the CDCC	Only de-identified
Protocols, CRFs, consents	Protocols, case report forms, consent forms, design documents.	No	No
Community focused materials	Brochures, story boards, educational materials, recruitment materials, etc.	Yes. These will be included in the publicly available RADx-UP Engagement Resource Center V	No
Qualitative data	Focus group materials, interviews, etc.	Pending evaluation by Northwestern University (June 2022)	Only de-identified, if feasible
Media publications	Public press, communication plans, etc.	No	No
Scientific publications	Manuscripts, abstracts, posters.	Yes. These will be included in the publicly available RADx-UP Engagement Resource Center ^v	No
Linked datasets	Area level external datasets like the American Community Survey linked to RADx-UP project data.	Yes	Yes
CDCC generated project metadata	Project details, weekly surveys reports, etc.	No	No

*https://radx-up.org/research/cdes/

^{**}These CDEs are required, but specific projects may have NIH-approved exceptions.

§ Projects will submit NIH RADx-UP Tier 1 CDE data to the CDCC at least quarterly. All other data will be submitted to the RADx-UP CDCC on a quarterly schedule.

^{§§}The CDCC will submit project data quarterly to the RADx Data Hub.

https://radx-up.org/resources