Clinical Trial Resources for COVID-19

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Agenda

- MHRA, EMA and FDA guidance for ongoing trials
- Medical Dictionary Terms Related to COVID-19
- Resources available for COVID-19 research
- CDISC Interim User Guide: COVID-19
- Resources for Public Health Researchers
- COVID-19 – Impact on ongoing trials

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MHRA, EMA and FDA guidance for ongoing trials

- Advice for ongoing trials affected by COVID-19:
- Protect:
- All decisions to adjust clinical trial conduct should be based on a risk assessment by the sponsor

➢ **Subject safety always prevails!**

- Collect:
- Collect relevant data in all clinical trials whether or not they study COVID-19. For example, include a specific reason for termination,

relevant laboratory tests, vital signs etc

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MHRA, EMA and FDA guidance for ongoing trials

- UK MHRA:

https://www.gov.uk/guidance/managing-clinical-trials-during-coronavirus-covid-19

- EU EMA:

https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/guidanceclinicaltrials_covid19_en.pdf

- USA FDA:

https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-guidance-conducting-clinical-

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Medical Dictionary Terms Related to COVID-19

- MSSO re-release of MedDRA 23.0 in April 2020
- COVID-19 terms added
- Recommendation is to re-download and implement the updated version of MedDRA 23.0
- MSSO presentation / webinar / recording are available here:

https://www.meddra.org/covid-19-information-page

Resources available for COVID-19 research

- CDISC works closely with pharmaceutical organizations around the globe to develop high-quality standards that ensure compliance with regulatory guidelines and create clarity in clinical research.
- As we evolve alongside the rapidly changing research landscape and welcomes new opportunities for innovation, we will continue to facilitate open, transparent communication about upcoming developments, provide educational opportunities to ensure the use of CDISC standards is as seamless as possible, and strive to make our standards even more beneficial for pharmaceutical organizations around the world.

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Resources available for COVID-19 research

- The benefits of implementing CDISC Standards in clinical research include:
- Fostered efficiency
- Complete traceability
- Enhanced innovation
- Improved data quality
- Facilitated data sharing
- Reduced costs
- Increased predictability
- Streamlined processes

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Resources available for COVID-19 research

- CDISC standards include many Therapeutic Areas relevant to COVID-19 research:
- Vaccines Therapeutic Area User Guide (TAUG)
  - Used to collect and report data in vaccines trials
- Cardiovascular Therapeutic Area User Guide (TAUG)
  - Used to collect and report data in CV trials
- Virology Therapeutic Area User Guide (TAUG)
  - Used to collect and report data in virology trials
- COVID-19 Interim Therapeutic Area User Guide (TAUG)
  - Used to collect and report data in COVID-19 trials
  - (interim – release 1.0 21Apr2020)

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Resources available for COVID-19 research

- Users need a CDISC subscription to access the Foundational standards, and additional Therapeutic Area User Guides
- Foundational Standards
  - https://www.cdisc.org/standards/foundational
- Vaccines Therapeutic Area User Guide (TAUG)
  - https://www.cdisc.org/standards/therapeutic-areas/vaccines
- Cardiovascular Therapeutic Area User Guide (TAUG)
  - https://www.cdisc.org/standards/therapeutic-areas/cardiovascular
- Virology Therapeutic Area User Guide (TAUG)
  - https://www.cdisc.org/standards/therapeutic-areas/virology

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CDISC Interim User Guide: COVID-19

- CDISC has released version 1.0 of the COVID-19 interim user guide, to assist collection and reporting of data for COVID-19 clinical trials on 21-Apr-2020
- The Interim User Guide for COVID-19 is freely available on the CDISC website without subscription, and describes the most common biomedical concepts relevant to COVID-19, and the necessary metadata to represent such data consistently including Terminology, CDASH, and SDTM
- CDISC Standards specify how to structure the data; they do not specify what data should be collected or how to conduct clinical trials, assessments or endpoints

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CDISC Interim User Guide: COVID-19

- The release includes (annotated) blank CRFs for data collection, SDTM mappings and terminology for COVID-19 trials, along with guidance for ongoing trials affected by COVID-19
- CDISC would like to express their profound gratitude to the task force participants for their involvement in the development of these resources:
- https://www.cdisc.org/covid-19-interim-user-guide-task-force

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CDISC Interim User Guide: COVID-19

Information for collection and reporting of COVID-19 related tests, including:

- 2 RISK FACTORS
- 3 ONSET OF DISEASE
- 4 SIGNS AND SYMPTOMS
- 5 LABORATORY TEST RESULTS
- 6 DIAGNOSTICS AND VIROLOGY
- 7 VITAL SIGNS AND URINE OUTPUT
- 8 CONCOMITANT MEDICATIONS
- 9 RESPIRATORY FINDINGS
- 10 CARDIAC EVENTS/FINDINGS
- 11 HOSPITALIZATION
- 12 PROCEDURES
- 13 VACCINES
- 14 QUESTIONNAIRES, RATINGS, AND SCALES

CDISC Interim User Guide: COVID-19

- COVID-19 Interim User Guide
- https://www.cdisc.org/system/files/members/standard/ta/COVID-19/Interim%20User%20Guide%20for%20COVID-19.pdf

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Resources for Public Health Researchers

- Resources for Public Health Researchers include Blank CRFs, Metadata and Terminology for use in COVID-19 trials
- https://www.cdisc.org/system/files/members/standard/ta/COVID-19/Resources%20for%20Public%20Health%20Researchers.zip

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COVID-19 – Impact on ongoing trials

- https://www.cdisc.org/system/files/members/standard/ta/COVID-19/Guidance%20for%20Ongoing%20Studies%20Disrupted%20by%20COVID-19.pdf
- Examples include:
- Add a new reason for discontinuation to the End of Study EDC page (DSDECOD)
- Redeploy EDC to include:
  - Additional Non-Standard Variables to capture COVID information e.g AEEPRELI
  - Additional lab tests, procedures and vital signs
- Implement MedDRA 23.0 re-release

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Thanks!

- If you are interested in joining the CDISC UK Network or contributing to our organizing committe, please email:
- cdiscUKnetwork@gmail.com

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