

DATA SHEET: Nucleus Coding

Medical Coding: Medical coding for MedDRA and WHODrug made easy

150

countries use the WHODrug dictionary to identify drug names and evaluate medicinal product information

Medical coding is performed to facilitate the summarizing and analysis of certain sets of data (e.g. Adverse Events, Medical History records, Concomitant Medications etc.). To provide control and consistency, a variety of medical coding dictionaries may be used to process, analyse, and report collected data.

Nucleus Coding enables dictionary term coding against both MedDRA and WHODrug dictionaries, either in our standalone application, or integrated into your data capture system.

How can Datatrial help your organisation?

Nucleus Coding – Datatrial will work with you to set up your instance in Nucleus and link the coding module to your chosen EDC system.

Dictionaries – These will be setup as standard ready for coding from the get-go to match your study requirements. The latest versions can be installed when they become available.

Support – We will support you throughout the on boarding process and beyond. You will be allocated a dedicated point of contact who will support you with set up, training and ongoing support.

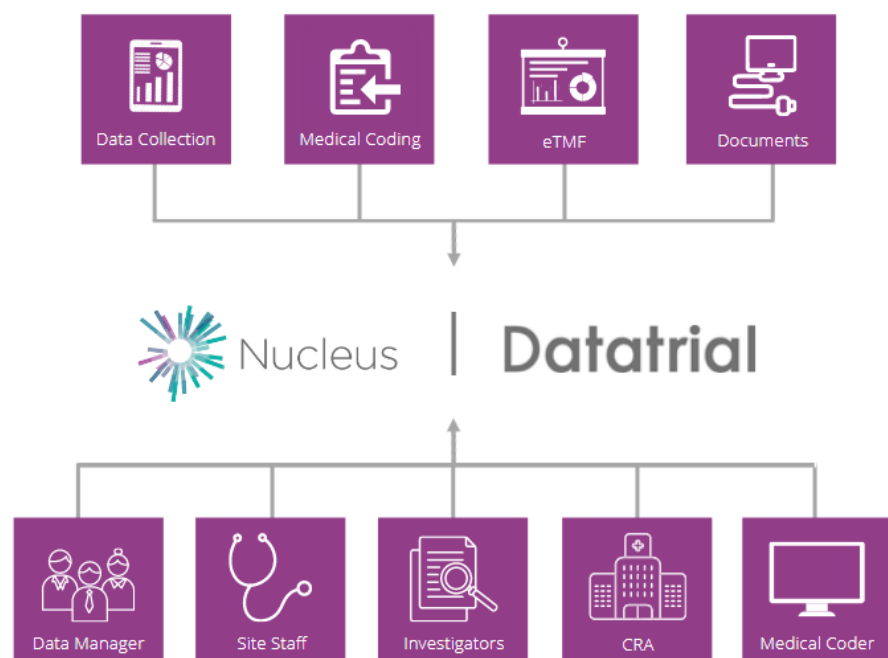
Quality and Compliance – Datatrial have a mature quality system and have been inspected by the MHRA in 2014. We have between 4-6 customer audits per year. Nucleus Coding has been built to comply with 21CFR Part 11 compliance and EU Annex 11.

Features and Benefits

70k

'Lowest Level Terms'
in the MedDRA
dictionary

- **Dictionary Management:** Manage versions and available dictionaries per study, to fit with your study protocol.
- **WHODrug Global:** WHODrug dictionary support to allow coding against medicinal product information. Just choose the dictionary version you require.
- **MedDRA:** Code against medical terminology given in the MedDRA database.
- **Automated term matching:** Terms are matched automatically where possible against the selected dictionary. Term names and non-unique drug names can be set up to auto code and be reviewed if required.
- **Term Review Queue:** Once coded, terms can be placed into a review queue for independent oversight of coded terminology. Review, Approve, Reject and Re-Code terms via the same intuitive selection process.
- **Dictionary Explorer:** Search inside dictionaries to help look up terms or identify items that require re-coding. Browse for both unique and non-unique terms and their related structures.
- **Standalone or Integrated:** Nucleus Coding can be used standalone or integrated into your EDC tool or data capture framework.
- **Public API (Application Programming Interface):** Use our publicly accessible and documented APIs to interrogate your coded data or directly code against dictionaries.



Challenges and Solutions

Accessible – Nucleus Coding can be accessed any time any place meaning you can code at your convenience

Configurable – Nucleus Coding can be used standalone or integrated into the EDC system of your choice and our dedicated team will help you with the set up

Regulatory Ready – To ensure that each role across a multi-site or global trial records information like adverse events (AE) in a standardised way, medical coding dictionaries standardize the language they use to report adverse events, medications and more so you are regulatory ready

Efficient – Save time and money and significantly speed up the clinical trial process by taking on dictionary management and ensure your always coding against the most up to date dictionary.

About Datatrial

At Datatrial we strive to make software that makes people's lives easier. With 20 years of experience in the life science industry our vision is to advance global healthcare using our data expertise, our innovative technology platform, and through striving to form collaborative relationships with the people we work with.

Datatrial provide software solutions enabling clinical organisations to better collaborate and safely capture, store, and analyse their trial data and information. We are passionate about both privacy and authenticity, and work with each of our commercial partners to ensure your data remain secure for the lifetime of your research.

Learn more at: <https://www.datatrial.com/nucleus/coding/>