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Monitoring
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– Building a global safety culture



WHODrug Vendor Programme

B3/C3 Format Approved Software Systems

Last updated: 26 May 2021

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The following software systems are all approved within the WHODrug Vendor Programme for handling B3/C3 format data. This is applicable for the version of the software that was approved and for future versions of the approved software that maintain the core specifications as the initial approved version. The software systems are listed in alphabetical order.

Acceliant

Software name and version: Acceliant, v. 7.0.2

Company: Trianz

Date of initial approval: January 17, 2017

Currently approved for format(s): B3

Description: Acceliant provides real-time, integrated clinical trial solutions for life sciences, CROs and pharma tools and expertise to take intelligent and smarter decisions. Its eClinical Suite allows users to build studies, design electronic case report forms (eCRFs), capture data through multiple sources (EDC), capture data directly from patients (ePRO), and manage other clinical data management functions.

agEncoder

Software name and version: agEncoder, v. 7.4.1 and v. 7.4.2

Company: ArisGlobal Software Pvt. Ltd.

Date of initial approval: December 16, 2011

Currently approved for format(s): B3

Description: agEncoder medical coding solution provides standard APIs and webservice, it receives verbatim terms from any compatible source system and performs auto-coding against specified medical dictionaries using advanced coding algorithms and defined synonyms. The coded terms are then sent back to the source. System supports adverse event term dictionaries (MedDRA) and product dictionaries (WHODrug, Japanese Drug Dictionary) and delivers upgrade/impact analysis and recoding.

Coding specialists can instantly resolve multiple records that use the same term, perform advanced searching, and manually code newly encountered verbatim terms.

Captivate

Software name and version: Captivate v.3.2

Company: ClinCapture Inc.

Date of initial approval: December 23, 2019

Currently approved for format(s): C3

Description: Captivate EDC offers privacy and performance to conduct studies of different complexities and budgets. Modules can be added to any package, such as the Captivate Coder for Medical Coding.

Central Coding

Software name and version: Central Coding 3.1.0.1 & 6.2

Company: Oracle America Inc.

Date of initial approval: May 28, 2010

Currently approved for format(s): B3/C3

Description: Central Coding will streamline the coding process. Provides customizable, multilingual, web-based coding and dictionary management software that alleviates the challenge of coding medical terms across clinical trial studies, regions, and languages.

CISYS WebCode

Software name and version: CISYS WebCode, v. 4.0

Company: CISYS LifeSciences, Inc.

Date of initial approval: April 11, 2013

Currently approved for format(s): B3

Description: Features and benefits:

- Browser agnostic Web-based platform
- API and web services based integration with external EDC platforms
- Extensive Dictionary Library with all historic and current versions of WHODDE and MedDRA
- Auto-Coding
- Robust customizable synonym list/thesaurus for both WHODDE and MedDRA coding
- Concurrent support of B2 and B3 formats
- Version Impact Analysis Tools that simplify version migration
- Can be integrated with most EDCs or used as a stand-alone coding solution
- Customized coding review and approval workflows
- Extensive query management system that supports manual, system, and up-version queries
- Ability to apply a code to all matching terms when coding a specific term
- Powerful dictionary search engine. Search by drug name, drug code, ingredient, ATC, preferred, generic, or trade
- Multilevel ATC coding
- Real-time access to coded data and coding metrics
- Point-and-click ease of use, user friendly GUI
- Highly configurable, standards based

ClinPlus Coding

Software name and version: ClinPlus Coding v. 3.2

Company: Anju ClinPlus, LLC

Date of initial approval: June 8, 2012

Currently approved for format(s): B3/C3

Description: A flexible clinical coding solution, ClinPlus® Coding is guaranteed to meet all of your adverse event and drug coding needs. ClinPlus Coding enables users to meet all their coding challenges with speed and accuracy. Our software leverages Microsoft .NET, SQL Server technology and the latest changes in dictionary formats and evolving industry requirements, yet still retains the reliability and flexibility ClinPlus users have come to expect.

Code Premier

Software name and version: Code Premier, V. 3.0.0

Company: EPS Corporation

Date of initial approval: August 22, 2015

Currently approved for format(s): B3

Description: Our propriety WHODrug Coding Tool was created from a coder's perspective. Developed through the cooperation of system engineers and coders with extensive knowledge of WHODrug, it offers easy-to-use search engines and adjustable settings.

Features:

- Increase hits with well-constructed search engine
- Auto-coding customization
- Precise drug and ATC code selection
- Synonym list management
- Version update including impact analyses and proper code selection
- Friendly tool to Japanese users

Coder2

Software name and version: Coder2, v. 2.0

Company: XClinical GmbH

Date of initial approval: October 4, 2017

Currently approved for format(s): B3/C3

Description: XClinical's auto-coding Software for WHODrug. Coder2 is a web-based tool to classify health-related data such as adverse events or concomitant medications. It includes standard WHODrug dictionaries to automatically and manually encode verbatim terms by use of powerful search mechanisms. The Coder2 provides an interface for seamless integration with EDC system such as XClinical's EDC system Marvin via a web service API, eliminating the import/export efforts for data managers. Coder2 includes a review workflow with 21CFR11-compliant signatures. Coded information can be transferred back to the EDC system to allow reporting and queries.

Coder2 key features:

- Web-based system, working on all modern standard browsers
- Versatile search engine for all elements of WHODrug like indication, dosage, ATC
- UMC-certified support for WHODrug B3 and C3 standards
- Automatic and manual coding including sponsor- or study specific set-ups
- Stand-alone web application – can be used independently of any EDC system
- Online participation of sponsor staff for review of difficult cases and validation
- Full audit trail documentation
- Project-based coding (multiple studies can use the same coding instance)

cubeCDMS®

Software name and version: cubeCDMS, v. 1.0

Company: CRScube Inc.

Date of initial approval: July 8, 2016

Currently approved for format(s): C3

Description: cubeCDMS® is a cutting-edge solution that comes fully equipped with powerful medical coding tools. Collect, store, and analyze clinical data through our cloud to enhance remote based site services. CRScube solutions are compliant with all relevant national regulations, and as a CDISC ODM certified member is devoted to improving e-data standards worldwide. With cubeCDMS® our sophisticated data representation software lets you view critical data naturally so that your study can take the steps needed to flourish.

Key features:

- eCRF can be created and deftly managed across all browsers
- Instant verification of data, and pre-packaged reports starts your analysis off the right way
- Improved monitoring functionality
- Workflow and Query generation
- Diverse coding dictionaries options
- WHODrug in the newly updated C3 format

cubeSAFETY

Software name and version: cubeSAFETY, v.1.0

Company: CRScube Inc.

Date of initial approval: February 24, 2021

Currently approved for format(s): C3

Description: cubeSafety® is a cloud-based system that streamlines the pharmacological reporting process; all the while being compliant with the regulations of regulatory agencies such as the EMA, PMDA, MFDS, CDE and FDA.

DATATRAK ONE

Software name and version: DATATRAK ONE, v. 14.2.2

Company: DATATRAK International

Date of initial approval: November 24, 2015

Currently approved for format(s): B3/C3

Description: The Medical Coding module within our EDC application provides easy online access to targeted medical coding dictionaries. The medical coding module is a single solution for dictionary management, searching, browsing, and batch or interactive coding, as well as generate user-defined synonyms for existing codes.

Dacima Clinical Suite

Software name and version: Dacima Clinical Suite, v. 3.3.10 and v. 3.3.11

Company: Dacima Software Inc.

Date of initial approval: November 17, 2017

Currently approved for format(s): B3/C3

Description: Dacima Clinical Suite is an off-the-shelf, fully featured electronic data capture (EDC) software that can be used for Randomized Clinical Trials, observational study designs, patient registries, web survey, electronic Patient Reported Outcomes (ePRO), and patient diaries. The software includes modules for interactive web randomization, emergency unblinding, drug allocation and inventory management, MedDRA and WHO Drug Dictionary coding.

DBMS Consulting Loading Scripts for Oracle TMS and Custom Query Tool

Software name and version: TMS v5.1.x and CQT

Company: DBMS Consulting, Inc.

Date of initial approval: September 28, 2011

Currently approved for format(s): Not applicable

Description: DBMS Consulting's Custom Query Tool (CQT) serves as a centralized system that will enable companies to create, maintain, and version their own Custom Query lists that are standard within their company as well as their own Custom Query lists specific to their medical products, customized to their safety analysis and regulatory reporting requirements.

DDworks21/EDC plus

Software name and version: DDworks21/EDC plus, v. 01

Company: Fujitsu Limited

Date of initial approval: October 18, 2016

Currently approved for format(s): B3

Description: tsClinical DDworks21/EDC plus is viewed as one of the industry's best EDC. We offer EDC plus and services not only to Japan customers but also global customers. EDC plus can help Monitor/DM/IT to improve data management efficiency while maintaining a high quality and low risk.

- EDC plus can implement master data centralized management with our industry-standard CTMS named tsClinical DDworks21/ASP
- EDC plus can implements data integration with our CDISC metadata management system (named tsClinical Metadata), risk-based monitoring approach visualization system (named Clinical Information) and EMR(Electronic Medical Record) system

eCaseLink

Software name and version: eCaseLink, v. 8.x

Company: DSG, Inc

Date of initial approval: February 14, 2013

Currently approved for format(s): B3

Description: eCaseLink™ EDC has been in continuous use by sites in 93 countries since 1999. It includes an automatic and interactive encoder, enabling credentialed users to perform all medical coding tasks within one fully integrated platform using the UMC dictionary versions for which they hold licenses.

eClinical MedCoder

Software name and version: eClinical MedCoder, v. 3

Company: Shanghai University of Traditional Chinese Medicine

Date of initial approval: December 28, 2020

Currently approved for format(s): B3

Description: eClinical MedCoder is an auto-coding Software. It supports automatically and manually coding with WHODrug and MedDRA dictionaries by use of powerful search mechanisms.

Key features:

- Stand-alone web application – can be used independently of any EDC systems.
- Automatic and manual coding including sponsor or study specific setups.
- Synonym list management for both WHODrug and MedDRA coding.
- Customized coding review and approval workflows.
- Dictionary Up-versioning.
- Full audit trail documentation.
- Friendly tool to Chinese users with intelligent recommendation for Chinese version.

Eclipse Coding

Software name and version: Eclipse Coding, Q3 2016 or later

Company: Eclipse Enterprise Solutions, LLC.

Date of initial approval: February 28, 2011

Currently approved for format(s): B3/C3

Description: Eclipse Coding is a web-based, centralized coding solution that can integrate with leading EDC and Safety applications for the conduct of medical and drug coding in clinical trials. Eclipse Coding's configurable workflow streamlines the coding process and improves coding turnaround time.

Key features:

- Manage and code with multiple dictionaries, versions and formats
- Code all studies at once or one at a time
- Multi-center connectivity in our world-class SaaS environment provides high performance for global coding teams
- Robust synonym management & Impact Analysis
- Advanced search functions for increased hit rates

eCollect

Software name and version: eCollect v5.10

Company: Zhejiang Taimei Medical Technology Co., LTD

Date of initial approval: November 7, 2016

Currently approved for format(s): B3/C3

Description: eCollect (Electronic Data Capture System) is a software system developed for pharmaceutical industries to effectively manage clinical data. Both Chinese and English versions of the software are available to meet regulatory requirements. Coding system including WHODrug and MedDRA are inbuilt in the softwares.

eSafety (eVigi)

Software name and version: eSafety (eVigi) v4.8

Company: Zhejiang Taimei Medical Technology Co., LTD

Date of initial approval: June 27, 2019

Currently approved for format(s): C3

Description: eSafety(eVigi) is a professional information system that can be applied to the field of pharmacovigilance in China and worldwide.

eSafety(eVigi) integrates clinical research and post-marketing product safety data and is committed to building a database of product safety information for the enterprise, safeguarding the company's products, effectively managing risks, and achieving the goal of ensuring patients' drug safety.

HALOPV

Software name and version: HALOPV 2.3

Company: Insife ApS

Date of initial approval: May 6, 2021

Currently approved for format(s): B3/C3

Description: HALOPV is a comprehensive drug safety system, capable of case intake, processing, submission as well as providing capabilities for aggregate reporting, regulatory intelligence, signal and risk management, PSMF, SDEA, literature monitoring etc. HALOPV is built on modern APIs and artificial intelligence for automation.

Haversac

Software name and version: Haversac 1.6.0

Company: Mediant Health, Inc.

Date of initial approval: September 21, 2017

Currently approved for format(s): B3

Description: Haversac Coding can work in tandem with Haversac EDC to ease query management, or as a stand-alone coding solution for imported records. Verbatim language is automatically loaded on record selection and search type and filters are single instant result choices. Coded records are segregated by a completed filter for easier workflow management, and coding time is automatically calculated to ease expense tracking.

iMedNet

Software name and version: iMedNet, v. 1.172.2

Company: MedNet Solutions, Inc.

Date of initial approval: July 3, 2014

Currently approved for format(s): B3

Description: iMedNet EDC is MedNet Solutions' latest EDC/eClinical technology platform. It provides nontechnical clinical research personnel with a fast, intuitive and cost-effective solution for building and managing clinical studies.

MainEDC

Software name and version: MainEDC 4.0

Company: Data Management 365, LLC

Date of initial approval: December 20, 2019

Currently approved for format(s): B3

Description: MainEDC system contains 3 components: EDC, IWRS and automated drug supply. One of the EDC component functionalities is a built-in medical coding tool, compatible and currently used with MedDRA, ATC and ICD-10 dictionaries. Our system's target users are Sponsor/CROs conducting clinical trials.

MedCodr

Software name and version: MedCodr, v. 1.0

Company: Prudentia Group LLC

Date of initial approval: October 30, 2017

Currently approved for format(s): B3/C3

Description: MedCodr is a web-based solution for coding medical verbatim terms and products to standard dictionaries including MedDRA and WHODrug or custom dictionaries. MedCodr provides a powerful, efficient and accurate auto-coding to verbatim to improve quality and consistency. It integrates with leading safety, clinical data management and EDC systems or in-house databases. Some of the features of MedCodr are:

- Supports multi-lingual dictionaries
- Configurable and efficient auto-coding
- Support for SDG, SMQ, and custom concepts
- Synonym management workflow with up-versioning
- Systematic impact assessment and coded data up-versioning
- Organize and share project/studies across users/groups
- Verbatim intake via manual, file, web method or database integration route
- Easy and intuitive user interface
- Supports multiple web browsers
- Metrics on quality/consistency of coding
- Audit log of all activities
- Hosted or on premise installation

Medrio

Software name and version: Medrio, v. 39.3

Company: Medrio, Inc.

Date of initial approval: April 25, 2012

Currently approved for format(s): B3

Description: Medrio EDC – Fast and flexible electronic data capture in your clinical trials, with you in charge. Handle database build, mid-study changes, and more with no reliance on programmers or external parties, unlocking essential speed and efficiency.

Nextrove

Software name and version: Oracle Arugs Safety 8.2.2

Company: Nextrove, LLC

Date of initial approval: October 9, 2020

Currently approved for format(s): Not applicable

Description: Nextrove responsibilities - We will be hosting the Argus Safety Database on our cloud platform and provide access to Sponsors and CROs who will do case processing and submission. Nextrove will be responsible for managing Argus database, uploading the WHODrug dictionary files whenever a new version is provided by UMC. Our key area of expertise is around Safety Database Management. We will also ensure that both CROs and well as Sponsor continue to have a current version of WHODrug by doing their annual audits and providing a copy to UMC for record keeping.

Octalsoft EDC

Software name and version: Octalsoft EDC 4.0

Company: Glorant India

Date of initial approval: May 25, 2021

Currently approved for format(s): B3/C3

Description: Octalsoft EDC is a comprehensive cloud-based software with a responsive layout that provides a simple user interface to capture trial subject data with ease. With integrated online edit checks and query management features, users can capture quality data with speed and accuracy. The system's powerful reporting capabilities help study teams visualize and analyze study data in real-time. By leveraging open standards, it allows for easy integration of clinical and non-clinical data from multiple sources.

Oracle Argus Safety Enterprise Edition

Software name and version: Oracle Argus Safety Enterprise Edition, v. 8.1.1-8.1.3, 8.2, 8.2.1

Company: Oracle America Inc.

Date of initial approval: September 8, 2017

Currently approved for format(s): B3/C3

Description: Argus Safety will help in achieving Compliance, Quality, and Efficiency in Safety Operations. Provides a comprehensive pharmacovigilance platform enabling manufacturers to make faster and better safety decisions, optimize global compliance, and integrate risk management into key processes.

Oracle Thesaurus Management System

Software name and version: Thesaurus Management System, v. 5.1.2/5.2.1

Company: Oracle America Inc.

Date of initial approval: July 25, 2017

Currently approved for format(s): B3/C3

Description: Oracle Thesaurus Management System (TMS) addresses the complexities associated with managing global thesauri. Designed to manage and classify free text captured during the drug development process, TMS meets the needs of multinational pharmaceutical, biotechnical, and medical device companies, contract research organizations, academic institutions, and regulatory authorities by providing a worldwide, scalable terminology repository.

- Global centralized terminology management
- TMS classification engine supports mapping verbatim terminologies to standard terminologies
- Supports outsourcing verbatim term classification tasks
- Supports custom or vendor supplied dictionaries
- Supports dictionary versioning and access to previous versions
- HTML browser provides enterprise-wide repository searching
- API-driven interface enables custom application integration
- Role-based security allows both data- and function related access
- Workflow implementation facilitates control and reporting of user activities

PACE

Software name and version: PACE, v. 3.3

Company: Clearight Information Systems, LLC

Date of initial approval: October 1, 2013

Currently approved for format(s): B3

Description: PACE is a web-based, advanced, multi-dictionary coding and management system that is designed to provide accurate and consistent coding output with increased productivity and quality. PACE's intelligent and self-learning synonym list automatically adapts itself to the coding conventions to ensure high auto-coding hit rate and the inbuilt scoring algorithm with suggestions helps to code and review terms more consistently and accurately with increased efficiency.

PACE can be integrated with any existing safety and clinical system. PACE can be used as central coding system to batch code both ongoing and legacy data (recoding). PACE supports multi version MedDRA & WHODrug along with any legacy or custom dictionaries. The in-built dictionary management tool helps manage loading and maintenance of dictionary versions with ease.

Features:

- Simultaneous multiple dictionary versions including MedDRA & WHODrug.
- In-built scoring algorithm with suggestion for accurate and consistent coding
- Integrate with any safety and clinical database
- Role based security and access with audit trail
- Rapid batch recoding
- E2B import / export for data exchange with external systems

PV-Works / PV-247

Software name and version: PV-Works (Saas solution branded as PV-247), v. 3

Company: Ennov PV

Date of initial approval: March 23, 2018

Currently approved for format(s): B3

Description: PV-247 is a comprehensive solution designed to meet all current regulations, including electronic reporting and safety surveillance, in a cost-effective package that is ready-to-go via the internet.

Rave Coder with ML

Software name and version: Rave Coder with ML, v. 2017.2.0

Company: Medidata Solutions, Inc.

Date of initial approval: June 18, 2018

Currently approved for format(s): B3/C3

Description: Rave Coder with ML is a cloud application that streamlines and centralizes medical coding. It works seamlessly with Medidata Rave and also integrates with any non-Rave EDC system.

REDCap Cloud

Software name and version: REDCap Cloud 1.4 and 1.5

Company: nPhase, Inc.

Date of initial approval: March 30, 2017

Currently approved for format(s): C3

Description: REDCap Cloud's Unified Data Management platform empowers organizations to collect, integrate, analyze and share health data in a standards-based way to make the right decisions at the right time. REDCap Cloud EDC is fully integrated in the platform and streamlines coding with WHODrug C and C3 format dictionaries.

Tara PV

Software name and version: TARA PV, v. 1.4.2

Company: MedGenesis Ltd

Date of initial approval: December 17, 2012

Currently approved for format(s): C₃

Description: TARA (Tools for Adverse Reaction Assessment) is a secure, powerful, and cost-effective web-based pharmacovigilance safety database, incorporating WHODrug and MedDRA dictionaries enabling accurate and efficient searching for coding of verbatim terms to improve data quality and analysis.

- Workflow and Role based security allows both data and function related access
- E2B import / export for regulatory reporting and data exchange with external systems
- Full system auditing capabilities
- Secure Tier 4 Cloud solution is provided on dedicated servers, managed and hosted by iDash Ltd.

Trial Data EDC

Software name and version: Trial Data EDC, v.6

Company: Trial Data Pharmaceutical Technology (Shanghai) Co., Ltd.

Date of initial approval: March 29, 2019

Currently approved for format(s): B₃

Description: Medical coding module within Trial Data EDC is a web based, centralized solution for coding medical verbatim terms and products to standard dictionaries including WHODrug and MedDRA with features as below:

- Support multi-dictionary version
- Automatic coding
- Intelligent recommendation of search results
- Batch coding
- Maintenance of Synonym
- Batch export of coding results for offline review or archiving
- Terms can link directly to the corresponding CRF for data cleaning and query maintenance

Trial Data also contains: IWRS for randomization and drug management; ERM system for trial risk management; EasyFu system for patient follow-up management etc.

TrialKit Coder

Software name and version: TrialKit Coder v. 4.6

Company: Crucial Data Solutions

Date of initial approval: August 22, 2016

Currently approved for format(s): B₃

Description: Designed to generate results at an unparalleled speed, TrialKit Coder is a highly configurable, accurate medical coding solution that is available on any web browser or mobile device.

Trial Online

Software name and version: Trial Online, v. 4.16

Company: Replior AB

Date of initial approval: March 24, 2017

Currently approved for format(s): C₃

Description: Trial Online is a secure, powerful, and cost-effective EDC service fully compliant with 21 CFR Part 11 and GCP. The solution is provided as Software As A Service solution on a dedicated server managed and hosted by Replior AB.

Vault Safety

Software name and version: Vault Safety 19R2

Company: Veeva Systems, Inc.

Date of initial approval: August 1, 2019

Currently approved for format(s): C₃

Description: Veeva Vault Safety Suite is a comprehensive pharmacovigilance cloud-based solution for managing the end-to-end drug safety lifecycle, enabling more efficient case intake and adverse event processing to authoring and seamless submissions. With a modern approach, it provides a scalable solution with superior user experience and greater visibility into safety cases and process status.

VIEDOC

Software name and version: VIEDOC, v. 4.38

Company: PCG Solutions AB

Date of initial approval: October 18, 2017

Currently approved for format(s): C₃

Description: Viedoc is the most modern EDC platform that can be found on the market and contains EDC, ePRO, randomization as well as medical and drug coding modules. The system is provided as a SaaS and allows customers to handle everything from study design and setup to study maintenance and lock completely on their own. Empower your clinical trial, contact us today.

Veeva Vault Coder

Software name and version: Veeva Vault Coder, v. 18R1+

Company: Veeva Systems, Inc.

Date of initial approval: July 16, 2018

Currently approved for format(s): B₃/C₃

Description: A modern, user-centric, and 100% cloud-based application, Veeva Vault Coder is the first true innovation in clinical coding in years. It provides an incredibly intuitive user interface, yielding fast, efficient, and correct coding for any type of clinical trial. Built on the Vault Unified Clinical Platform and seamlessly integrated with Veeva Vault EDC, it supports coding eCRFs with all versions of the WHODrug B₃, WHODrug C₃, and MedDRA dictionaries. Features include:

- Autocoding
- Batch Coding
- Suggestions
- Synonym Lists
- Dictionary Search
- Verbatim Search
- Queries with in-product discussion threads
- Dictionary Up-versioning
- Metrics on Progress and Prioritization
- Role-Based Security
- Audit Trail

INSPIRE. ENGAGE. TRANSFORM.

Uppsala Monitoring Centre advances the science of pharmacovigilance and inspires patient safety initiatives all over the world. As an independent, non-profit foundation, we engage stakeholders who share our vision and collaborate to build a global patient safety culture. As a leader in the research and development of new scientific methods, we explore the benefits and risks of medicines to help minimise harm to patients, and offer products and services used by health authorities and life-science companies worldwide. Our unique expertise makes us an organisation with the capacity to transform patient safety from an ambition into a reality. For almost 40 years, we have provided scientific leadership and operational support to the WHO Programme for International Drug Monitoring, expanding the global pharmacovigilance network to reach more than 95% of the world's population (www.who-umc.org).



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