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Monitoring
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– Building a global safety culture

WHODrug Software Certification Programme

B3/C3 Format Certified Software Systems

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The following software systems are all certified within the WHODrug Software Certification Programme for handling B3/C3 format data. The software systems are listed in alphabetical order.

agEncoder

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

Company: ArisGlobal Software Pvt. Ltd.

Date of original certification: December 16, 2011

Date of B3/C3 certification: December 19, 2017

Certified for format(s): B2/B3/C

Description: agEncoder medical coding solution provides standard APIs and webservices, 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.

Central Coding

Software name and version: Central Coding 3.1.0.1 & 6.2

Company: Oracle America Inc.

Date of original certification: May 28, 2010

Date of B3/C3 certification: October 16, 2018

Certified for format(s): B2/C/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 original certification: April 11, 2013

Date of B3/C3 certification: June 29, 2017

Certified for format(s): B2/B3/C

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 original certification: June 8, 2012

Date of B3/C3 certification: January 16, 2018

Certified for format(s): B2/B3/C/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.

Clinical Studio csCoder

Software name and version: Clinical Studio csCoder v. 4.4.1

Company: Crucial Data Solutions

Date of original certification: August 22, 2016

Date of B3/C3 certification: February 22, 2017

Certified for format(s): B2/B3

Description: Stand-alone medical coding tool for importing data, coding terms via configurable workflow, managing synonyms, reviewing codes, updating data, up-versioning dictionaries, and exporting data. csCoder can be used independent of the Clinical Studio EDC or as an integral part of the data collection.

A perfect tool for medical coding professionals who need one comprehensive platform that can be configured and assessed from anywhere.

Clinical Studio csCoder Mobile

Software name and version: Clinical Studio csCoder Mobile

Company: Crucial Data Solutions

Date of original certification: August 22, 2016

Date of B3/C3 certification: March 8, 2017

Certified for format(s): B2/B3

Description: The only mobile app packed with all the same medical coding functionality you would expect on the desktop version.

Run auto-coding, review terms, browse dictionaries, and manage synonyms from a device you keep in your pocket.

Code Premier

Software name and version: Code Premier, V. 3.0.0

Company: AC MEDICAL INC.

Date of original certification: August 22, 2015

Date of B3/C3 certification: March 8, 2017

Certified for format(s): B2/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 WHO DD, 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

The software descriptions in this document has been directly provided by the certified software vendors and UMC accepts no liability for accuracy, spelling mistakes or omissions.

Coder2

Software name and version: Coder2, v. 1.0

Company: XClinical GmbH

Date of B3/C3 certification: October 4, 2017

Certified for format(s): B2/C/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 original certification: July 8, 2016

Date of B3/C3 certification: December 14, 2016

Certified for format(s): C/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

DATATRAK ONE

Software name and version: DATATRAK ONE, v. 14.2.0

Company: DATATRAK International

Date of B3/C3 certification: April 16, 2018

Certified for format(s): B2/B3/C/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 B3/C3 certification: November 17, 2017 (C3); August 16, 2018 (B3)

Certified for format(s): C/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 Outomes (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.

DDworks21/EDC plus

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

Company: Fujitsu Limited

Date of B3/C3 certification: September 15, 2017

Certified for format(s): B2/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 original certification: February 14, 2013

Date of B3/C3 certification: June 11, 2018

Certified for format(s): B2/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.

Eclipse Coding

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

Company: Eclipse Enterprise Solutions, LLC.

Date of original certification: February 28, 2011

Date of B3/C3 certification: November 23, 2016

Certified for format(s): B2/B3/C/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

iMedNet

Software name and version: iMedNet,v. 1.172.2

Company: MedNet Solutions, Inc.

Date of original certification: June 3, 2014

Date of B3/C3 certification: August 23, 2017

Certified for format(s): B2/B3

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

MedCodr

Software name and version: MedCodr, v. 1.0

Company: Prudentia Group LLC

Date of B3/C3 certification: October 30, 2017

Certified for format(s): B2/B3/C/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

Oracle Argus Safety Enterprise Edition

Software name and version: Oracle Argus Safety Enterprise Edition, v. 8.1.1

Company: Oracle America Inc.

Date of B3/C3 certification: September 8, 2017

Certified for format(s): B2/B3/C/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.

Box 1051, SE-751 40 Uppsala, Sweden

Tel: +46 18-65 60 60 www.who-umc.org

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Oracle Thesaurus Management System

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

Company: Oracle America Inc.

Date of B3/C3 certification: July 25, 2017

Certified for format(s): B2/B3/C/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 original certification: October 1, 2013

Date of B3/C3 certification: October 9, 2017

Certified for format(s): B2/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

Rave Coder with ML

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

Company: Medidata Solutions, Inc.

Date of B3/C3 certification: June 18, 2018

Certified 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.

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Trial Online

Software name and version: Trial Online, v. 4.16

Company: Replior AB

Date of B3/C3 certification: March 24, 2017

Certified for format(s): C/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.

Veeva Vault Coder

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

Company: Veeva Systems, Inc.

Date of B3/C3 certification: July 16, 2018

Certified 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

VIEDOC

Software name and version: VIEDOC, v. 4.38

Company: PCG Solutions AB

Date of original certification: October 18, 2017

Date of B3/C3 certification: December 18, 2017

Certified for format(s): C/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.

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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).

Uppsala Monitoring Centre (UMC)
Box 1051, SE-751 40 Uppsala, Sweden
Tel: +46 18-65 60 60 www.who-umc.org