



**PROMETRIKA**

A FULL-SERVICE CRO

**Innovative Clinical Development Solutions**

# Study Conduct Medical Coding

November 9, 2017

# Introduction

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PROMETRIKA Rave Coder® Platform  
Accreditation March 2017

Medidata Coder Implementation Experience

PROMETRIKA Medidata Coder Implementation Manual  
Creation

Rave® Coder Advantages

# Coder vs. Vendor Stand Alone Coder

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Maps verbatim terms from Adverse Events, Concomitant Medications and Medical History to specific terms in industry standard dictionaries (i.e., MedDRA, WhoDrug). Integrated with Medidata Rave EDC. Direct transmission between Coder and Rave EDC.

In contrast, other coder products are built independently and externally from the EDC and then the data is integrated in a secondary process.

# Advantages of Medidata Coder

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The Coder application includes a number of configurable parameters for defining the application roles, coding workflow, and dictionary and synonym list management

The integration allows for real time auto-coding, manual coding, creation of synonyms, posting queries directly to the site, reclassify a term (recode), perform coding consistency review and generate coding consistency listings

Coding consistency review can be performed on an ongoing basis that allows for faster review and feedback about coding assignments

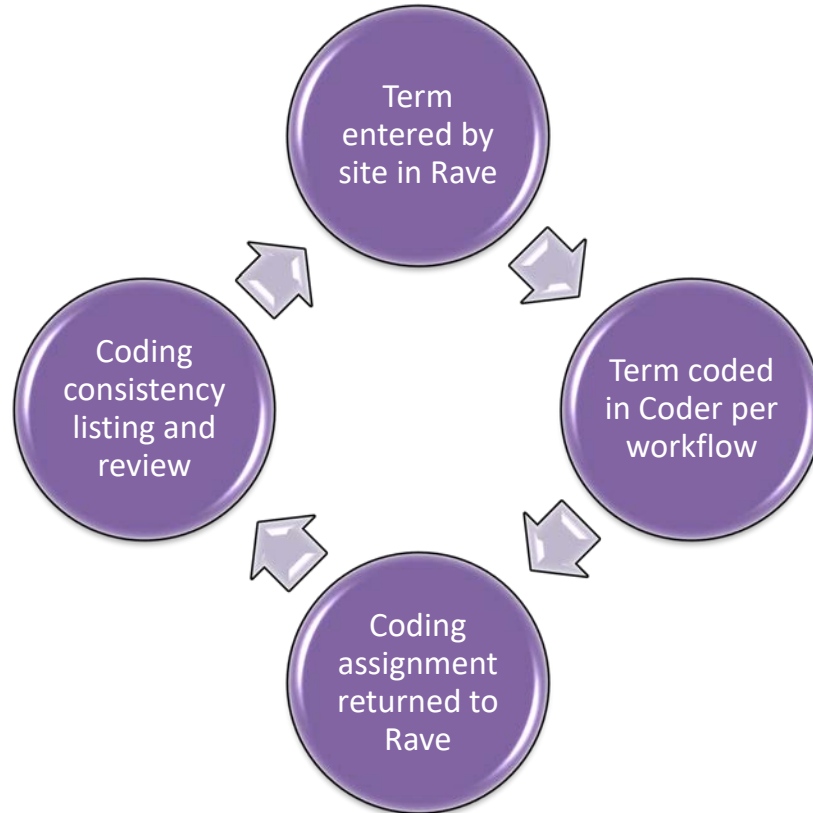
# Coder Configurable Parameters

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- Manual provides procedural steps for implementing Coder through UAT
- Coder and application roles
- Coder segment, dictionary management (Licensure) and Coder workflow
  - Set up coder segment
  - Set up of dictionary versions to be used
  - How terms are coded
- Synonym list management
  - Creation and management

# Integration of Rave and Coder

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Term  
entered by  
site in Rave



Subject: 9998-1002

Page: Medical and Surgical History - Screening

Inactivate Page



Did the Patient report any relevant medical or surgical history conditions or events?

Yes

*If Yes, add a log line to report each significant medical, surgical, psychiatric, neurological condition, or treatment.*

| # | Medical History Condition/ Event | Start Date | Start Date Completely Unknown       | Ongoing                  | End Date | End Date Completely Unknown         |  |
|---|----------------------------------|------------|-------------------------------------|--------------------------|----------|-------------------------------------|--|
| 1 | Fractured Left Leg               |            | <input checked="" type="checkbox"/> | <input type="checkbox"/> |          | <input checked="" type="checkbox"/> |  |

[Printable Version](#) [View PDF](#) [Icon Key](#)

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Save

Cancel



Term coded in Coder per workflow



1 Coding Tasks Found 1 Coding Tasks Selected

| Verbatim Term      | Group | Priority | Status              | Assigned Term | Dictionary                                  | Queries | Time Elapsed |
|--------------------|-------|----------|---------------------|---------------|---------------------------------------------|---------|--------------|
| FRACTURED LEFT LEG | 1     | 3        | Waiting Manual Code |               | MedDRA - 20.0 - Study<br>MH<br>MedDRA_v20.0 |         | 0.5 days     |

[Open Query](#)
[Add Comment](#)
[Browse And Code](#)

| Source Terms |       | Properties    | Assignments | Coding History     | Query History  |          |                   |                              |
|--------------|-------|---------------|-------------|--------------------|----------------|----------|-------------------|------------------------------|
| Source Sy:   | Study | Dictionary    | Locale      | Term               | Level          | Priority | Name              | Value                        |
| Rave EDC     | Study | MedDRA - 20.0 | ENG         | Fractured Left Leg | Low Level Term | 3        | Field             | MHTERM                       |
|              |       |               |             |                    |                |          | Line              | 1                            |
|              |       |               |             |                    |                |          | Form              | Medical and Surgical History |
|              |       |               |             |                    |                |          | Event             | VISIT2                       |
|              |       |               |             |                    |                |          | Subject           | 9998-1002                    |
|              |       |               |             |                    |                |          | Site              | Test Site 9998               |
|              |       |               |             |                    |                |          | Supplemental Term | Supplemental Value           |

Coding assignment returned to Rave



Subject: 9998-1002

Page: Medical and Surgical History - Screening

Inactivate Pa



Did the Patient report any relevant medical or surgical history conditions or events?

Yes

*If Yes, add a log line to report each significant medical, surgical, psychiatric, neurological condition, or treatment.*

|   | Medical History Condition/ Event                                                                                                                                                                                                           | Start Date | Start Date Completely Unknown       | Ongoing                  | End Date | End Date Completely Unknown         |                                                                                                                              |
|---|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|-------------------------------------|--------------------------|----------|-------------------------------------|------------------------------------------------------------------------------------------------------------------------------|
| 1 | Fractured Left Leg<br>SOC 10022117 Injury, poisoning and procedural complications<br>HLGT 10005942 Bone and joint injuries<br>HLT 10075886 Limb fractures and dislocations<br>PT 10061599 Lower limb fracture<br>LLT 10024128 Leg fracture |            | <input checked="" type="checkbox"/> | <input type="checkbox"/> |          | <input checked="" type="checkbox"/> | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> |

Coding consistency listing and review



Medical History Coding Consistency Listing

| Subject | Form            | Record Position | Medical History Verbatim | Lower Level Term (LLT) | Lower Level Term Code | Preferred Term (PT) | Preferred Term (PT) Code | System Organ Class (SOC)                       | System Organ Class (SOC) Code | High Level Group Term (HLGT) | High Level Group Term (HLGT) Code | High Level Term (HLT)           | High Level Term (HLT) Code | Dictionary Version |
|---------|-----------------|-----------------|--------------------------|------------------------|-----------------------|---------------------|--------------------------|------------------------------------------------|-------------------------------|------------------------------|-----------------------------------|---------------------------------|----------------------------|--------------------|
| C01-006 | Medical History | 1               | 5th metatarsal fractures | Fractured metatarsal   | 10017298              | Foot fracture       | 10016970                 | Injury, poisoning and procedural complications | 10022117                      | Bone and joint injuries      | 10005942                          | Limb fractures and dislocations | 10075886                   | MedDRA 19.1        |

# Real Time Coding

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- Auto-coding
  - Direct dictionary match
  - Synonym list match
- Manual coding
  - Create synonyms
    - Auto coding hit rate increases when more synonyms are in the synonym list
  - Post coding queries to the site to clarify verbatims
  - Reclassify a term (re-code)
  - Run coding consistency listings

# Coding Consistency Review

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- Performed on an ongoing basis
- Faster feedback about coding assignments
- Sponsors see codes in Rave with read-only role
- Synonym approval: First step of quality control for review of coding
  - “Activate synonym” before term can be used for auto-coding
  - Lists created & used for auto-coding verbatims without a direct dictionary match
  - Can be retired at any time during the coding process

# Real Time Review

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- Internal review
- Sponsor review
- Medical Monitor review
- Safety Review meetings
- Data Monitoring Committee meetings

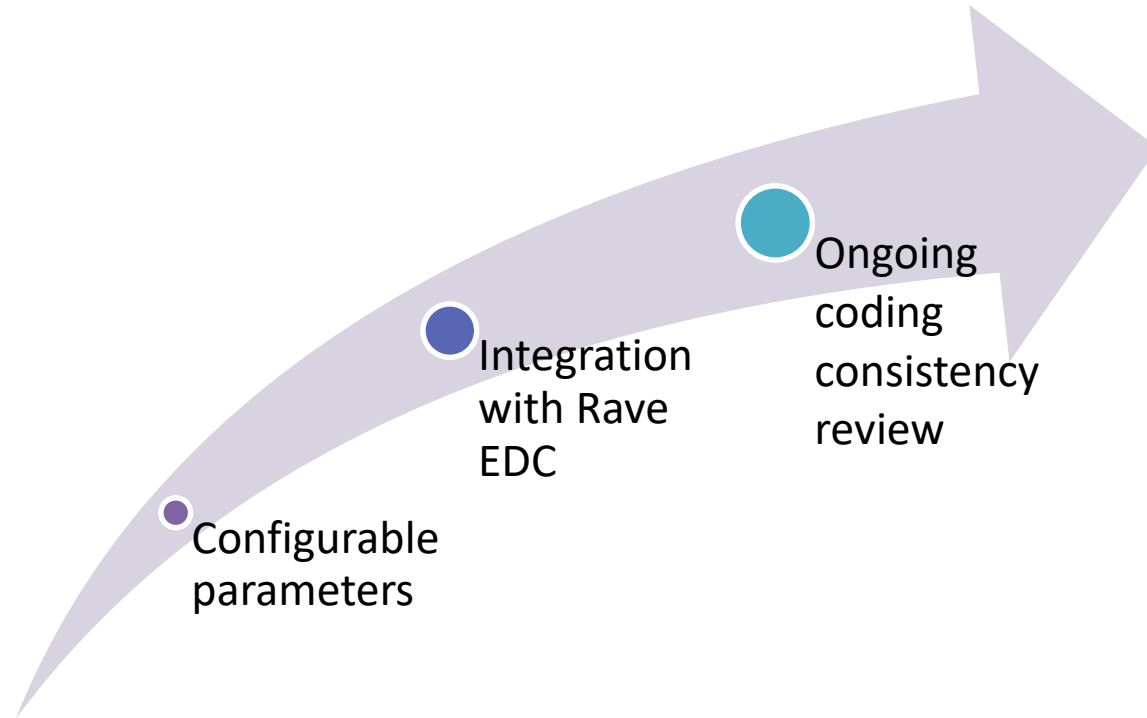
# Coding Listings & Reports

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- Custom coding consistency listings created
  - Reviewers only see coding assignment information
- Other coding reports available
  - Metric reports - number of coded terms
  - Coding completion - all terms coded
  - Synonym list approvals
  - Reclassification complete

# In Summary

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# PROMETRIKA “NEXT”

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- Adding Coder to an existing study
  - Previous coding performed in dsNavigator
  - Uploading synonym lists created from dsNavigator export files
    - Planned for end of 2017
- Dictionary up-versioning
- Implement external verbatim management (the Medidata stand alone Coder) for use on NDA submissions where up-versioning is required

# Questions