Innovative Clinical Development Solutions
Study Conduct Medical Coding

November 9, 2017
Introduction

PROMETRIKA Rave Coder® Platform
Accreditation March 2017

Medidata Coder Implementation Experience

PROMETRIKA Medidata Coder Implementation Manual Creation

Rave® Coder Advantages
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

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

- 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

1. Term entered by site in Rave
2. Coding consistency listing and review
3. Coding assignment returned to Rave
4. Term coded in Coder per workflow

The process flows from left to right, indicating a seamless integration between Rave and Coder.
Term entered by site in Rave

Subject: 9998-1002  
Page: Medical and Surgical History - Screening

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.*

<table>
<thead>
<tr>
<th>#</th>
<th>Medical History Condition/ Event</th>
<th>Start Date</th>
<th>Start Date Completely Unknown</th>
<th>Ongoing</th>
<th>End Date</th>
<th>End Date Completely Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Fractured Left Leg</td>
<td>✓</td>
<td></td>
<td></td>
<td>✓</td>
<td></td>
</tr>
</tbody>
</table>

Printable Version  View PDF  Icon Key

<table>
<thead>
<tr>
<th>Term coded in Coder per workflow</th>
</tr>
</thead>
</table>

### 1 Coding Tasks Found

<table>
<thead>
<tr>
<th>Verbatim Term</th>
<th>Grop</th>
<th>Priority</th>
<th>Status</th>
<th>Assigned Term</th>
<th>Dictionary</th>
<th>Queries</th>
<th>Time Elapsed</th>
</tr>
</thead>
<tbody>
<tr>
<td>FRACTURED LEFT LEG</td>
<td>1</td>
<td>3</td>
<td>Waiting Manual Code</td>
<td>Study</td>
<td>MedDRA - 20.0 - MH</td>
<td></td>
<td>0.5 days</td>
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</tbody>
</table>

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### Source Terms

<table>
<thead>
<tr>
<th>Source Sy</th>
<th>Study</th>
<th>Dictionary</th>
<th>Locale</th>
<th>Term</th>
<th>Level</th>
<th>Priority</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rave EDC</td>
<td>Study</td>
<td>MedDRA - 20.0</td>
<td>ENG</td>
<td>Fractured Left Leg</td>
<td>Low Level Term</td>
<td>3</td>
</tr>
</tbody>
</table>
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.

<table>
<thead>
<tr>
<th>Medical History Condition/ Event</th>
<th>Start Date</th>
<th>Start Date Completely Unknown</th>
<th>Ongoing</th>
<th>End Date</th>
<th>End Date Completely Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fractured Left Leg</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SOC 10022117 Injury, poisoning and procedural complications</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>HLGT 10005942 Bone and joint injuries</td>
<td>✔️</td>
<td></td>
<td>✔️</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HLT 10075886 Limb fractures and dislocations</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PT 10061599 Lower limb fracture</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>LLT 10024128 Leg fracture</td>
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<td></td>
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<tr>
<td>Subject</td>
<td>Form</td>
<td>Record Position</td>
<td>Medical History Verbatim</td>
<td>Lower Level Term (LLT)</td>
<td>Lower Level Term Code</td>
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<tr>
<td>----------</td>
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<tr>
<td>C01-006</td>
<td>Medical History</td>
<td>1</td>
<td>5th metatarsal fractures</td>
<td>Fractured metatarsal</td>
<td>10017298</td>
</tr>
</tbody>
</table>
Real Time Coding

- 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

- 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 verbatim without a direct dictionary match
  - Can be retired at any time during the coding process
Real Time Review

- Internal review
- Sponsor review
- Medical Monitor review
- Safety Review meetings
- Data Monitoring Committee meetings
Coding Listings & Reports

- 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

- Configurable parameters
- Integration with Rave EDC
- Ongoing coding consistency review
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