ICH Guidelines

M4 →
E9 ←
Q7 ←
Q12 ←
M8 ↑
M1 ↑
E17 →
E5 →
E2 →
E6 →

ICH Day
5月20日  | 北京国际会议中心
May 20   | Beijing International Convention Center

DIA
Getting Ready for Polling (准备投票)

- 打开手机
- 打开 internet browser
- 输入网址：PollEv.com/meddra174
- 不用输入名字
- 开始投票
- 投票是匿名的
Are You A

- Coder 编码员
- Drug safety specialist 药物安全专员
- Clinical data manager 临床数据管理员
- Medical advisor 医学顾问
- Manager 管理人员
- Statistician 统计师
- Other 其他
Your MedDRA Experience

- 经常使用MedDRA
- 偶尔使用MedDRA
- 从未使用MedDRA
MedDRA, the Process of MedDRA Coding in CT, and Coder Qualifications

Anna Zhao-Wong, MD PhD  Joy Zhu
Deputy Director  Medical Officer
MedDRA MSSO  MedDRA MSSO
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Agenda

- Part I – MedDRA fundamentals and the ICH-Endorsed MedDRA Coding Guide
- Part II – The Process of MedDRA Coding in CT and Coder Qualifications – a company’s experience
Part I: MedDRA fundamentals and the ICH-Endorsed MedDRA Coding Guide
What is MedDRA?

Med = Medical
    D = Dictionary for
    R = Regulatory
    A = Activities

MedDRA is a clinically-validated international medical terminology used by regulatory authorities and the regulated biopharmaceutical industry (药监部门和制药业). The terminology is used through the entire regulatory process (整个监管过程中), from pre-marketing to post-marketing, and for data entry (数据输入), retrieval (检索), evaluation, and presentation (展示).
What is MedDRA? (cont)

- MedDRA is owned by ICH
- Distributed by the MSSO via subscription
  - Subscription rates are decided by ICH
- Subscribed via online subscription form: [https://www.meddra.org/subscription/subscription-form](https://www.meddra.org/subscription/subscription-form)
- MSSO is based in McLean, Virginia USA
- MSSO representative in China is Joy Zhu, who is based in Beijing
- Ways to contact the MSSO
  - Email: mssohelp@meddra.org
  - WeChat: Chinese MedDRA User Group (2 groups), MSSO 公众号
MedDRA Users

~5,800 Subscribing organizations in 125 countries

<table>
<thead>
<tr>
<th>Country</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>United States</td>
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</tr>
<tr>
<td>Japan</td>
<td>793</td>
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<tr>
<td>United Kingdom</td>
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<tr>
<td>Germany</td>
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<td>South Korea</td>
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<td>Australia</td>
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<td>Sweden</td>
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<tr>
<td>India</td>
<td>93</td>
</tr>
<tr>
<td>Switzerland</td>
<td>87</td>
</tr>
</tbody>
</table>
Medical conditions
Indications (适应症)
Investigations (检查, 检查结果)
手术及医疗操作
病史, 家史, 社会史
Medication errors (用药错误)
产品质量问题
医疗器械相关问题
产品使用问题
药物基因学 terms
Toxicologic (毒理) issues
标准 MedDRA 分析查询 (SMQs)
Frequency qualifiers
Numerical values for results
Severity descriptors
Not a drug dictionary
Patient demographic terms
Clinical trial study design terms
Not an equipment, device, diagnostic product dictionary
## ICH E2B(R3) Data Elements Use MedDRA

### E2B (R3) - ICSR

#### Clinical Trials, Post market

<table>
<thead>
<tr>
<th>Element ID</th>
<th>E2B(R3) Element Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>B.1.7.1.r.a.2</td>
<td>Structured Medical History Information (disease / surgical procedure / etc.)</td>
</tr>
<tr>
<td>B.1.8.r.f.2</td>
<td>Indication</td>
</tr>
<tr>
<td>B.1.8.r.g.2</td>
<td>Reaction</td>
</tr>
<tr>
<td>B.1.8.4.b.1</td>
<td>Reported cause(s) of death</td>
</tr>
<tr>
<td>B.1.9.4.r.b.1</td>
<td>Autopsy-determined cause(s) of death</td>
</tr>
<tr>
<td>B.1.10.7.1.r.a.2</td>
<td>Structured information (disease / surgical procedure / etc.) - parent/child report (parent)</td>
</tr>
<tr>
<td>B.1.10.8.r.f.2</td>
<td>Indication - parent/child report (parent)</td>
</tr>
<tr>
<td>B.1.10.8.r.g.2</td>
<td>Reactions (if any and known) - parent/child report (parent)</td>
</tr>
<tr>
<td>B.2.i.1.b</td>
<td>Reaction/event in MedDRA terminology</td>
</tr>
<tr>
<td>B.3.r.c.2</td>
<td>Test Name (MedDRA code)</td>
</tr>
<tr>
<td>B.4.k.7.r.2.a</td>
<td>Indication in MedDRA terminology</td>
</tr>
<tr>
<td>B.5.3.r.2</td>
<td>Sender’s diagnosis/syndrome and/or reclassification of reaction/event</td>
</tr>
</tbody>
</table>
MedDRA Translations

10019211

Electronic Submission

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血液及淋巴系统疾病
心脏器官疾病
各种先天性家族性遗传性疾病
耳及迷路类疾病
内分泌系统疾病
眼器官疾病
胃肠系统疾病
全身性疾病及给药部位各种反应
肝胆系统疾病
免疫系统疾病
感染及侵染类疾病
各类损伤、中毒及手术并发症
各类检查
代谢及营养类疾病

• 各种肌肉骨骼及结缔组织疾病
• 良性、恶性及性质不明的肿瘤（包括囊状和息肉状）
• 各类神经系统疾病
• 妊娠期、产褥期及围产期状况
• 产品问题
• 精神病类
• 肾脏及泌尿系统疾病
• 生殖系统及乳腺疾病
• 呼吸系统、胸及纵隔疾病
• 皮肤及皮下组织类疾病
• 社会环境
• 各种手术及医疗操作
• 血管与淋巴管类疾病
MedDRA Coding

System Organ Class (SOC) (27)

High Level Group Term (HLGT) (337)

High Level Term (HLT) (1,737)

Preferred Term (PT) (23,708)

Lowest Level Term (LLT) (80,262)

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MedDRA Version 22.0
ICH-Endorsed MedDRA Coding Guide

- MedDRA Term Selection: Points to Consider
- Maintained by ICH M1 Expert Working Group
- Available on MedDRA.org
- Provides term selection advice for industry and regulatory purposes
- Objective is to promote accurate and consistent term selection to facilitate a common understanding of shared data
- Recommended to be used as basis for individual organization’s own coding conventions

MedDRA® TERM SELECTION:
POINTS TO CONSIDER
ICH-Endorsed Guide for MedDRA Users

Release 4.17
Based on MedDRA Version 22.0

1 March 2019

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ICH-Endorsed MedDRA Coding Guide (cont)

- MedDRA TS:PTC also addresses important issues like
  - Quality of Source Data
  - Quality Assurance
  - Do Not Alter MedDRA
  - Term Selection Principles

- Direct impact to the quality of coding
Autoencoder Pitfalls

Inappropriate terms may be selected by autoencoder

• “Allergic to CAT scan” autoencoded as:
  LLT *Allergic to cats*

• “Myocardial infarction in the fall of 2000” autoencoded as:
  LLT *Myocardial infarction*
  LLT *Fall*
### Diagnoses and Provisional Diagnoses

<table>
<thead>
<tr>
<th>SINGLE DIAGNOSIS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>DEFINITIVE DIAGNOSIS</strong></td>
</tr>
<tr>
<td>Single diagnosis without signs and symptoms</td>
</tr>
<tr>
<td>• Diagnosis (only possible option)</td>
</tr>
</tbody>
</table>

**Example:** "Myocardial infarction" → select "Myocardial infarction"

**Example:** "Possible myocardial infarction" → select "Myocardial infarction" (select term as if definitive diagnosis)
ICH-Endorsed MedDRA Coding Guide (cont)

Diagnoses and Provisional Diagnoses (cont)

<table>
<thead>
<tr>
<th>SINGLE DIAGNOSIS</th>
<th>DEFINITIVE DIAGNOSIS</th>
<th>PROVISIONAL DIAGNOSIS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single diagnosis with signs/symptoms</td>
<td>Single diagnosis with signs/symptoms</td>
<td>Single provisional diagnosis with signs/symptoms</td>
</tr>
<tr>
<td>• Preferred: Diagnosis only</td>
<td>• Preferred: Provisional diagnosis and signs/symptoms</td>
<td></td>
</tr>
</tbody>
</table>

Example: “Anaphylactic reaction with rash, dyspnoea, hypotension, and laryngospasm” → select “Anaphylactic reaction”

Example: “Possible myocardial infarction with chest pain, dyspnoea, diaphoresis” → select “Myocardial infarction” “Chest pain”, “Dyspnoea”, and “Diaphoresis”
### SINGLE DIAGNOSIS

<table>
<thead>
<tr>
<th>DEFINITIVE DIAGNOSIS</th>
<th>PROVISIONAL DIAGNOSIS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single diagnosis with signs/symptoms</td>
<td>Single provisional diagnosis with signs/symptoms</td>
</tr>
<tr>
<td>• Alternate: Diagnosis and signs/symptoms</td>
<td>• Alternate: Signs/symptoms only (as provisional diagnosis may change)</td>
</tr>
</tbody>
</table>

Example: “Anaphylactic reaction with rash, dyspnoea, hypotension, and laryngospasm” → select “Anaphylactic reaction”, “Rash”, “Dyspnoea”, “Hypotension”, and “Laryngospasm”

Example: “Possible myocardial infarction with chest pain, dyspnoea, diaphoresis” → select “Chest pain”, “Dyspnoea”, and “Diaphoresis”
ICH-Endorsed MedDRA Coding Guide (cont)

**Do not make diagnosis if only signs/symptoms reported**

<table>
<thead>
<tr>
<th>Reported</th>
<th>LLT Selected</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdominal pain, increased serum amylase, and increased serum lipase</td>
<td>Abdominal pain</td>
<td>It is inappropriate to assign an LLT for diagnosis of “pancreatitis”</td>
</tr>
<tr>
<td></td>
<td>Serum amylase increased</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Lipase increased</td>
<td></td>
</tr>
</tbody>
</table>
After MedDRA Coding

Sorted cases

- SOC Infec
  - HLGT Infec - pathogen unspec
  - HLT Abdo & gastroint infec
  - PT Pancreatic abscess
    - LLT1
    - LLTA
  - PT Pancreatitis acute
    - LLT2
    - LLTB
  - PT Pancreatic necrosis
    - LLTC

- SOC Gastr
  - HLGT Exocrine pancreas condi
    - HLGT3
    - HLT Abdo & gastroint infec
    - PT Pancreatitis acute
    - PT Pancreatic necrosis
    - LLT1
    - LLTA
    - LLT2
    - LLTB
    - LLTC
  - HLGT4

- SOC3
  - HLT3
  - HLT4
  - PT3
  - PT4

- SOC4
  - LLT3
  - LLT4

- Case1
  - Case2
  - Case3
  - Case4
  - Case5
  - Case6
  - Case7
  - Case8
  - Case9
  - Case10
  - Case11
  - Case12
  - Case13
  - Case14
Part II: The Process of MedDRA Coding in CT and Coder Qualifications – a company’s experience
Agenda

• Coding in Clinical Trials
• Purpose of Coding Process
• Roles and responsibilities
• Data Coding Plan
• Coder Professional Qualification
Coding in Clinical Trials
Coding in Clinical Trials

Study Design
- Protocol
- Case Report Form
- Technical Designer

Study Conduct
- Clinical Research Coordinator
- Coder
- Clinical Research Associate
- Investigator
- Data Manager
- SAE Reconciliation
- Pharmacovigilance
Purpose of Coding Process
Purpose of Coding Process

Accuracy

Consistency
Roles and Responsibilities
Roles and Responsibilities

- Coder
- Data Team Lead
- Biostatistician
- Clinical Lead
- Programmer
- Medical Data Reviewer
- Independent Coding Reviewer
Data Coding Plan
Data Coding Plan

- Data to be coded
- Dictionaries and versions
- Coding and coding review process
- General coding guidelines
- Sponsor or project specific coding conventions
Data Coding Plan

- Data to be Coded
Data to be Coded

Clinical Database

- Screening
  - I/E Criteria
  - Demography
  - Medical History
  - Baseline Characteristics

- Therapy
  - Study Drug Administration
  - Concomitant Medication
  - Concomitant Procedures
  - Therapy Compliance

- Efficacy
  - Base on Protocol
  - Indication

- Safety
  - Adverse Events
  - Lab Results
  - Vital Signs
  - Reason of Death

MedDRA

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Data Coding Plan

- Dictionaries and Versions
Dictionaries and Versions

Dictionaries:
- MedDRA
- WHODrug Dictionary
- Other dictionaries (Sponsor specific)

Dictionary license validation
MedDRA Data Sharing

- Subscription grants access to MedDRA for one year
- Subscriber cannot grant any sublicense, publish or otherwise distribute MedDRA to a third party
- Data may be freely exchanged between current MedDRA subscribers
  - Sponsor-sponsor, sponsor-CRO, vendor-user, etc.
  - Use Self-Service Application to check organization’s subscription status
- Sharing MedDRA with a non-subscribing organization is a violation of the MedDRA license
Check Organization Status

**How to Use It**
- Enter your organization's MedDRA ID and password to retrieve the subscription status.
- After user authentication process, the user can retrieve other organization subscription status with MedDRA.
- Use the Import button for retrieving multiple organizations' subscription status in one attempt.

<table>
<thead>
<tr>
<th>MedDRA ID</th>
<th>Submit</th>
<th>Import</th>
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</thead>
<tbody>
<tr>
<td>10290</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Organization</th>
<th>Current Subscriber</th>
<th>Renewal Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>IQVIA</td>
<td>Yes</td>
<td>May</td>
</tr>
</tbody>
</table>
Two MedDRA updates/year

- 1 March X.0 (Complex release)
  - 15 March – Translations

- 1 September X.1 (Simple release)
  - 15 September - Translations
MedDRA Versioning Plan – Options:

1. “Freeze” at the initiation and for the life of a project and report with same version.
2. “Freeze” at the initiation of a project and report with most recent version.
3. “Freeze” at the initiation of each trial within a project, and report with the most recent version.
4. “Freeze” at the beginning of each trial within a project and optionally re-code data with the latest version at the conclusion of the trial based on criteria defined within project plan. Always output the data utilizing the most recent version.
5. Hold all coding to the completion of each trial and utilize the most recent for coding and reporting.
6. Re-code the trial data for all trials in a project on an ongoing basis with the most recent version.

MSSO recommends Option 5 or 6 (*MedDRA Best Practices 2018*)
### Dictionaries and Versions (cont.)

<table>
<thead>
<tr>
<th>Options</th>
<th>Freeze</th>
<th>Report</th>
<th>Up-version</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Initiation and for the life of a project</td>
<td>Same version</td>
<td>No</td>
<td>Consistency of coding and analysis</td>
<td>Old version</td>
</tr>
<tr>
<td>2</td>
<td>Initiation of a project</td>
<td>Most recent version</td>
<td>Once</td>
<td>New version; Consistency of coding and analysis</td>
<td>Significant differences in between</td>
</tr>
<tr>
<td>3</td>
<td>Initiation of each trial within a project</td>
<td>Most recent version</td>
<td>Once</td>
<td>New version</td>
<td>Significant differences in between</td>
</tr>
<tr>
<td>4</td>
<td>N/A, Hold all coding to the completion of each trial</td>
<td>Most recent version</td>
<td>No</td>
<td>Consistency of coding</td>
<td>Significant workload stress at the end; No analysis before the end</td>
</tr>
<tr>
<td>5</td>
<td>Beginning of each trial within a project</td>
<td>Most recent version</td>
<td>At milestones</td>
<td>New version</td>
<td>Ongoing workload</td>
</tr>
<tr>
<td>6</td>
<td>No freeze</td>
<td>Most recent version</td>
<td>Ongoing basis</td>
<td>Always new version; No reconciliation issues with PV</td>
<td>Ongoing workload</td>
</tr>
</tbody>
</table>
These methods should not be interpreted as regulatory requirements but may be used to communicate effectively between and within organisations.

<table>
<thead>
<tr>
<th>Method</th>
<th>Description</th>
<th>Resource Intensity</th>
<th>Data Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Begin to use new version for coding new data; no recoding of existing data</td>
<td>Least</td>
<td>Least</td>
</tr>
<tr>
<td>2</td>
<td>Identify verbatim terms linked to non-current LLTs and recode existing data</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Identify verbatim terms linked to non-current LLTs and recode existing data and Recode verbatim terms to new LLTs that are direct or lexical matches</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Identify verbatim terms linked to non-current LLTs and recode existing data and Recode verbatim terms to new LLTs that are direct or lexical matches and Recode verbatim terms to new LLTs that are more accurate concepts</td>
<td>Most</td>
<td>Most</td>
</tr>
</tbody>
</table>
Dictionaries and Versions (cont.)

MedDRA Version Analysis Tool (MVAT)

- Web-based (https://tools.meddra.org/mvat)
- Free to all users
- Features
  - Version Report Generator (produces exportable report comparing any two versions)
  - Data Impact Report (identifies changes to a specific set of MedDRA terms or codes uploaded to MVAT)
  - Search Term Change (identifies changes to a single MedDRA term or code)
- User interface and report output available in all MedDRA languages
Data Coding Plan

- Coding and Coding Review Process
Process Map – Study Initiation

Create Data Coding Guidelines

Data Team Lead

Start

Determine key points depending on finalized Case Report Form (CRF)

Create Project specific Data Coding Guidelines (DCG)

Program and Test Project Specific Coding Set-up

Lead Coder

Request user access to the coding application

Ensure Review of DCG; obtain authorization

Request Coding Set-up

Perform formal testing of coding application

Create final testing comments log indication “no errors identified”

Yes

No

Errors identified?

Correct errors identified

Record errors on the testing comments log

File the documents

Review all testing documentation; Authorize its use in production

Ouruser access to the coding application

Errors identified?

Record errors on the testing comments log

Correct errors identified

Prepare test environment of coding application

Develop test environment of coding application

Programmer

Produce and test the project specific coding application

Develop test environment of coding application

Correct errors identified
Process Map – Ongoing during study conduct

Manage Coding, Coding Queries and Document Uncoded Data

Data Team
Lead

Coder

Cont A

Autocode process fails?

Yes

No

Identify terms that remain uncoded

No

Yes

Can term be coded?

Query answer appropriate?

No

Manually review term

Yes

Communicate decision to coder: document the list of terms that remain uncoded

Answer query

Can term require query?

Yes

Generate a manual query in EDC system

No

Manually assign most appropriate code

Perform an independent coding review

Contact Sponsor to determine appropriate action

Code or remain uncoded?

Yes

No

Close the query in EDC

Investigator/
Site Staff
Process Map – Study Finalization

**Study Finalization**

Data Team Lead

End

File the documents

Ensure coding application access is revoked at DBL

Coder

Perform an independent coding review

Take action according to coding review comments

Interim / Final Database Lock?

Yes

Sponsor / Medical Data Reviewer

Review of coded data by Medical Data Reviewer

Review of coded data by Sponsor

Approve coded data by Sponsor
Data Coding Plan

- General Coding Guidelines
General Coding Guidelines

Coding will be carried out in adherence with MedDRA Term Selection: Points to Consider, the ICH-Endorsed Guide for MedDRA Users.

General Points:
- Misspelling
- Translations
- Abbreviations and Acronyms
- Combination Terms
General Coding Guidelines (cont.)

- **Medical/Surgical Procedures** Reported as an *Adverse Event*
  - Code to the procedure?
  - Query to provide a diagnosis?

- **Medical/Surgical Procedures** and **Medical Condition** Reported in Combination as a *Medical History*
  - Code to the medical condition?
  - Query to split, and code both?
General Coding Guidelines (cont.)

- Body Site vs. Event Description
- Location vs. Infectious Agent
- Congenital vs. Acquired

- Accidental Injuries
  - Code to the injury?
  - Code to the accident?
  - Query to split, and code to both?
Data Coding Plan

- Sponsor or Project Specific Conventions
Sponsor or Project Specific Conventions

Allergy Coding

- If, due to (e)CRF/database design or specifications, allergies are reported under Allergies but listed only as, e.g., Penicillin or Pollen, it is acceptable to use this information to code the term to Penicillin Allergy or Pollen Allergy as the term cannot be modified.

Drug/Substance Abuse Coding

- If, due to (e)CRF/database design or specifications, drugs/substances are reported under Abuse, but listed only as, e.g., Alcohol or Caffeine, it is acceptable to use this information to code the term to Alcohol Abuse or Caffeine Abuse as the term cannot be modified.
Chest Pain

• Code to Chest pain?
• Query to specify the type?
  • Cardiac chest pain
  • Non-cardiac chest pain
  • Musculoskeletal Chest Pain
• Depend on the panel / form?
  • Adverse event – query
  • Medical history – not query
Coder Qualification
Core Responsibilities

• Perform Medical Coding
• Validates/tests the coding set up and programming of coding reports
• Write and resolve data clarifications
• Manage coding related project timelines
• Bring coding and project related solutions
• Develop and maintain good communications and working relationships with the DM team, Medical team, Biostatistical team, and Clinical Operation team.
Coder Qualification - Required knowledge, skills and abilities

- Thorough knowledge of Medical Terminology
- Thorough knowledge of Medical Dictionaries used for coding
- Excellent organizational, communication and leadership skills
- Ability to exercise excellent attention to detail and act independently with the initiative required to resolve problems
- Basic understanding of database technologies related to data management and coding
- Ability to work on computer systems with ease and good working knowledge of computer programs
Coder Qualification – Training System

**Medical Terminology**
- Word Structure
- Suffixes
- Prefixes
- Organization of the Body
- Body Systems

**Coding Dictionaries**
- MedDRA Term Selection: Points to Consider
- Company coding conventions
- Other dictionaries

**Process**
- Develop Data Coding Guidelines
- Test/Validate Coding Set-up
- Query Management
- Dictionary update

**Tools**
- Coding Platforms
- Electronic Data Capture (EDC) Systems
- Other tools for generating reports / comparing data

**Soft skills**
- Project Management
- Communication
- Leadership
- Self-promotion
Coder Qualification - Career Ladder

**Trainee**
- 6~8 weeks’ training
- Final test

**Mentee**
- 6~8 months’ mentoring
- Ongoing evaluation

**Coder**
- 6~8 months’ supervising
- Ongoing evaluation

**Lead Coder**
- Lead Projects independently
- Perform coding review