Codex: Up-Version 8.3

BKP Codex: Up-Version, a MedDRA up-versioning tool from BKP Technologies, Inc. provides a robust solution for life sciences companies that need to up-version MedDRA/MedDRA J coded terms in Oracle Argus Safety™ to new dictionary versions.   Regular up-versioning of MedDRA-coded safety data streamlines regulatory compliance and enhances signal detection capabilities by standardizing safety data. BKP Codex: Up-Version supports a proven workflow built around industry best practices for analyzing, reviewing/updating, and batch up-versioning MedDRA coded terms using a friendly web-based interface.

Features - At a Glance

- Fully integrated with Oracle Argus Safety™ 8.x
- Supports Argus Multi-Tenant
- Supports any version of MedDRA
- Full support for Japanese coding with Argus J and MedDRA J
- Industry proven workflow:
  - Analysis of coded term changes
    - Configurable analysis algorithm
    - Changed terms marked for review
  - Review of term up-versioning instructions
    - Interactive review of term changes
    - Manual coding can override algorithm
  - Batch application of up-version instructions to Argus Safety database
    - Fast execution minimizes downtime
    - Preserves Argus audit trail integrity
- Comprehensive reports of up-version decisions and results
- Complete set of quality documentation to support fully validated use of BKP Codex: Up-Version as a 21 CFR 11, Annex 11 and HIPAA compliant system

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BKP Technologies, Inc. is an industry leader with over 15 years of experience providing coding tools and services. Contact us for a no-cost demonstration!
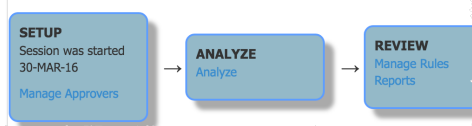
Industry Proven Workflow

BKP Codex: Up-Version implements a rule-based workflow, where an up-versioning rule is created for for each distinct verbatim/code pair. These rules can be interactively reviewed, approved or overridden, based on user access roles and then applied in batch to the Argus database.

SESSION: "Test"
Argus Instance: **ut8012**, Up-version to **17.1J**, Analysis Executed: 30-Mar-2016 0
Require manual approval: Only when LLT becomes non-current, Recode to Prim
Non-current LLTs:Attempt Verbatim Coding/Leave Uncoded
Uncoded J terms: Automatically Code to MedDRAJ, Non-Current J LLTs: Recod
Datatype(s): Company Diagnosis, Cause of Death, Event, Lab Data, Historical C
Indication, Vaccine Prior AE, Always Serious Term List, Datasheet Listed Term, L
Current Status: **Active**

SETUP
Session was started
30-MAR-16
Manage Approvers

→ **ANALYZE**
Analyze

→ **REVIEW**
Manage Rules
Reports

- Automated analysis of coded terms generates up-versioning rules
  - Unchanged MedDRA term rules are automatically approved
  - Changed MedDRA term rules are flagged for review
- Manual review and coding/override of rules
- Up-Versioning session level approvals via e-signatures
- Comprehensive reports provide decision support, including display of where each verbatim/code pair appears in Argus
- Batch application of dictionary up-versioning to Argus Safety database based on approved decisions

Comprehensive Reporting

Built-in reports provide detailed information at each step of the up-versioning process.

- Up-versioning decision support
  - Comprehensive onscreen display of all recoding rules
  - Interactive reporting on where terms are used in the Argus Safety database
  - Comparison of event term and data sheet coding to identify mis-matches
  - Summary reports off all rules by status for offline review
- Pharmacovigilance reporting
  - Distinct preferred term usage report
  - Summary reports of all Adverse Event PT changes across database or by product
- Audit Trail
  - Fully integrated with Argus Safety audit trail for case and configuration data
  - Full auditing of BKP Codex: Up-Version configuration, manual coding, and review/approval process supports 21 CFR 11 and Annex 11 compliance

Coded Term:	Asthenia		**Status:** Auto-approved

Coded Term (J): 無力症

Rule Usage: Datasheet Listed Term;

Old: LLT: Asthenia (10003549); PT: Asthenia (10003549); HLT: Asthenic conditions (1 administration site conditions (10018065);

Old J: LLT: 無力症 (10003549); PT: 無力症; HLT: 無力症; HLGT: 全身障害ＮＥＣ; SOC:

New: LLT: Asthenia (10003549); PT: Asthenia (10003549); HLT: Asthenic conditions (administration site conditions (10018065);

New J: LLT: 無力症 (10003549); PT: 無力症; HLT: 無力症; HLGT: 全身障害ＮＥＣ; SOC

Coded Term:	Ataxia		**Status:** Auto-approved

Coded Term (J): 運動失調

Rule Usage: Lab Data;

Old: LLT: Ataxia (10003591); PT: Ataxia (10003591); HLT: Coordination and balan disorders (10029205);