

## Summary of Changes for the 2014Q3 Quarterly Data Extract

Below is a list of all the changes that will be included in the 2014Q3 Quarterly Data Extract (QDE). This document is to provide stakeholders with an advanced look at the new data fields that will be provided.

### XML

- Added new tag for <authoritynumb> populated with Regulatory Authority's case report number, when available
- Added new tag for <literaturereference> populated with Literature Reference information, when available
- Added new tag for <drugrecuration> populated with the Reaction/Event information if/when <drugrecurreadministration> equals 1
- Added new tag for <patientagegroup> populated with Patient Age Group code as follows, when available:

<u>CODE</u>	<u>MEANING</u>	<u>TEXT</u>
1	Neonate	
2	Infant	
3	Child	
4	Adolescent	
5	Adult	
6	Elderly	

- Added new tag for <activesubstance> populated with Product Active Ingredient, when available
- Added new tag for <narrativeincludeclinical> tag populated with Case Event Date, when available; does NOT include Case Narrative.
- Modified the <patientsex> tag LOV removing the value of 9 (Not Specified)

### ASCII

- Added new field for Authority Number (AUTH\_NUM) in Demographic file populated with Regulatory Authority's case report number, when available
- Added new field for Literature Reference (LIT\_REF) in Demographic file populated with Literature Reference information, when available
- Added new field for Age Group (AGE\_GRP) field in Demographic file populated with Age Group code as follows, when available:

<u>CODE</u>	<u>MEANING</u>	<u>TEXT</u>
N	Neonate	
I	Infant	
C	Child	
T	Adolescent	
A	Adult	
E	Elderly	

- Added new field for Product Active Ingredient (PROD\_AI) in Drug file populated with Product Active Ingredient, when available
- Added new field for Drug Recur Action (DRUG\_REC\_ACT) in Event file populated with the Reaction/Event information if/when Rechallenge equals Y (Positive Rechallenge)
- Modified field header from GNDR\_COD to SEX in Demographic file

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NOTE: Readme files will be updated to include details about the newly added and modified XML tags/ASCII fields