ICSR Testing Criteria Selection Chart

This template is used to capture high-level ICSR testing criteria based upon current functionality provided in the standard. Organizations interested in DSTU testing should complete the chart and forward to the project sponsor so that all test scenarios can be reviewed by the project team. Questions concerning this template should be sent to Lise Stevens at: Lise.Stevens@fda.hhs.gov.

TEMPLATE INSTRUCTIONS

Please complete the template using the following definitions describing ICSR reporting scenarios:

Submission Type: An indication of the content (payload) of the ICSR message. The possible categories are:

- **Individual submission:** Assumes that the transmitter will send one ICSR message instance at a time as a separate file or individual transmission.
- **Batch submission:** Assumes that the transmitter will send several ICSRs in one batch submission

Report Type: An indication of the characteristics of the transmission in reference to the sender/receiver work flow. This relates to the ICSR interactions supported in the message. The possible categories are:

- Initial
- Follow-up
- Retraction

Investigated Subject Entity Type: This describes the type of investigative subject(s) of the ICSR report. The possible categories are:

- Person
- Animal
- Group

ICSR Incident Type: An indication of the underlying activity that is being reported. The possible categories are:

- Adverse Event
- Product Problem

Product Type: Describes the type of product(s) referenced in the report. The possible categories are:

- Human Drugs: Which includes therapeutic biologics and vaccines
- Animal Drugs

- Medical Devices
- Food, food additives and nutritional supplements
- Cosmetics
- Combination products

ICSR Content Coding Requirements: An indication of the coding used in the ICSR report. The possible categories are:

- Coded data: Please indicate whether or not will use internal codes to code observations in the ICSR. Examples of places where coding could be used: Reactions, Clinical Observations, Lab tests, and Concurrent Observations
- Text only: Assumes no additional coding is required

Using the above information please complete the following table using the example format:

Testing Organization	Submission Type	Report Type	Investigated Subject Entity Type	ICSR Incident Type	Product Type	Coding requirements
Sterling Tester A1	*Individual*	*Initial*	*Person*	*AE*	*Drug*	*Coding required using MedDRA*
	Individual	*Follow-up*	*Person*	*AE*	*Drug*	*Coding required using MedDRA*
	Batch	Initial	Animal & Group	Product Problem	Drug	Text only