



# MedDRA and “Modifiers”

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# What and Why

- A modifier is a term that can optionally be applied to a MedDRA term to modify the meaning
  - Aggravated, exacerbated, recurrent, acute, ...
- MSSO continues to get requests about adding new terms with modifiers
- EFPIA (Barry Hammond – GSK) initially developed this idea and continues to back it




## What and Why (cont)

- Even though E2b is not open to edit right now, be prepared and have subscriber involvement prior to E2b version update
  - Identifies E2b requirements
  - Allows for subscriber involvement



# Potential “Modifiers” classification

<p>A) Modifiers that do not change the original concept, does not alter the primary SOC, and have little or no impact on data retrieval or analysis.</p>	<p>Group I: disease progression</p>	<p>acute_chronic; aggravated_exacerbated_worsening; improved; mild_moderate_severe; progression_progressive; extreme; recurrent; relapse; intermittent; continuous; reentrant; symptomatic; asymptomatic; history_of_family history_of_no family history of; frequent; rare_occasional; senile_elderly; juvenile; grade 1-2-3 &amp; 4.</p>	
	<p>Group II: disease systemization</p>	<p>bacteraemia of, viraemia of</p>	
	<p>Group III: disease etiology</p>	<p>Primary_idiopathic; secondary; nosocomial</p>	
	<p>Group IV: anatomical location</p>	<p>Unilateral; bilateral; multiple</p>	



# Group I: Disease progression

- acute/ chronic
- aggravated/ exacerbated/ worsening
- improved
- mild/ moderate/ severe
- progression/ progressive
- extreme
- recurrent
- relapse
- intermittent
- continuous
- reentrant
- symptomatic
- asymptomatic
- history of/ family history of/ no family history of
- frequent
- rare/ occasional
- senile/ elderly
- juvenile
- grade 1, 2, 3 & 4



# ICH “Points to Consider” document

- **Pre-existing medical conditions** that have changed
  - If no modified term exists in MedDRA, one of the following three options may be employed:

**Option 2:** Select term for condition **AND** a separate modifier term. E.g., “*Progression of Alzheimer’s disease*” → select “*Alzheimer’s disease*” **AND** “*Disease progression NOS*”



# Potential “Modifiers” classification

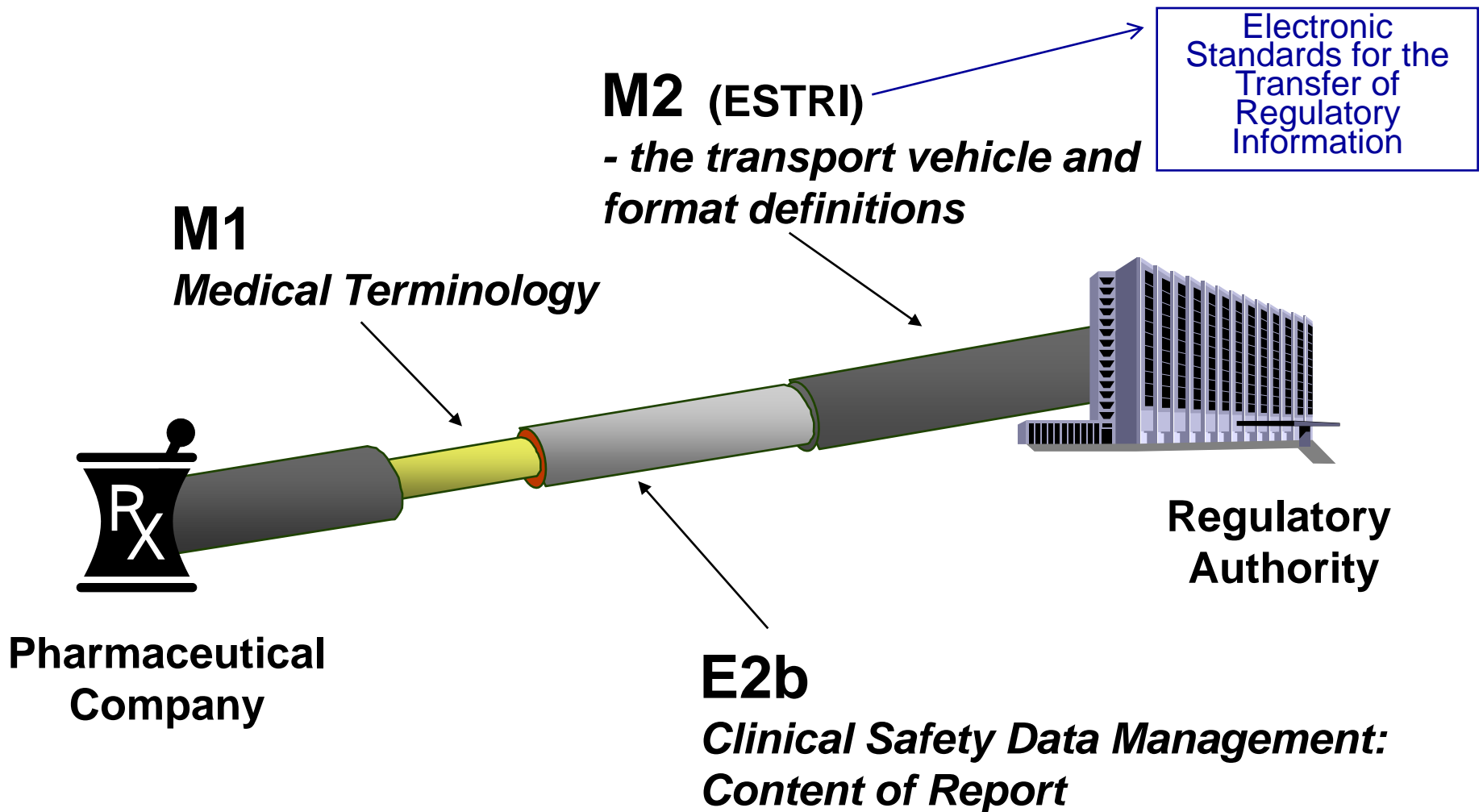
<p><b>B) Modifiers that do change the original concept, and lead to a different primary SOC. This group will have a big impact on how to retrieve and analyze data.</b></p>	prophylaxis of	Indicates treatment: SOC Surgical and medical procedures
	Neonatal	linkage to SOC Pregnancy, puerperium and perinatal conditions
	traumatic of	Not a drug related event. Link to SOC Injury, poisoning and procedural complications
	Infective	Indicates infection: SOC Infections and infestations
	postoperative/ postprocedural	indicates a complication after a medical procedure -> HLGT Procedural and device related injuries and complications NEC
	Interoperative	
	intraoperative	
	congenital/ familial	if a disease occurs mostly pathological, this modifier will change the modified term's primary SOC to Congenital SOC.
acquired	if a disease occurs mostly congenital, this modifier will change the modified term's primary SOC to site of manifestation (or infection, neoplasm whichever applies)	



# Potential “Modifiers” classification

<p><b>C) Investigation</b>  <b>SOC: it can be approached by two different methodologies regarding modifiers</b></p>	<p>Approach one: The test results are the modifiers and test names + anatomical location (if needed) + specimen are the MedDRA terms in this SOC</p>	<ul style="list-style-type: none"> <li>-increased/ decreased</li> <li>-normal/ abnormal</li> <li>-positive/ negative</li> <li>-Prolonged</li> </ul>
	<p>Approach two: The specimen are modifiers and test names + anatomical location (if needed) + results are the MedDRA terms in this SOC</p>	<ul style="list-style-type: none"> <li>-blood</li> <li>-urine</li> <li>-stool</li> <li>-CSF</li> <li>-Hair</li> </ul>

# ICH EDI Coordination





# ICH “Points to Consider” document

- Medical/Surgical procedures (Optionally can code **both** diagnosis and procedure) ..
- Location & Infectious agent
- “Medication error”  
“Overdose”/“Toxicity”/“Poisoning”  
  
– (+) “Condition”/“No adverse event”



# Next Steps

- MSSO to complete draft Modifier document
- Circulate to MedDRA MB
- Circulate to MedDRA community
- Continue coordination with PTC and E2b working groups
- Communicate progress through MSSO website and emails to subscribers