



# **USER´S GROUP MEETING - MSSO**

**“Scope of MedDRA” break out  
session**

**5<sup>TH</sup> annual  
User Group Meeting, Rome  
March 5-7, 2003**



# Scope of MedDRA

**OUT**

**IN**

**Diseases  
Diagnoses  
Signs  
Symptoms**

**Therapeutic indications  
Investigation names & qualitative  
results**

**Medical & surgical procedures  
Medical, social, family history**

**Terms from:  
COSTART<sup>©</sup>  
WHO-ART<sup>©</sup>  
HARTS<sup>©</sup>**

**Drug product terms**

**Population-level qualifiers**

**Patient demographic  
terms**

**Numerical values for  
results**

**Device failure terms**

**Severity descriptors**

**Clinical trial study design terms**

**Equipment, device,  
diagnostic product terms**



# Out of MedDRA ¿? ...

A. Drug product terms	E. Population –level qualifiers
B. Patient demographic terms	F. Numerical values for results
C. Clinical trial study design terms	G. Severity descriptors
D. Device failure terms	H. Equip, device, diagnostic product terms



# Out of MedDRA ¿? ...

<p>A. Drug product terms</p>	<ul style="list-style-type: none"><li>■ We include subclasses – but no names. For example, “Anticonvulsant drug level”</li></ul>
<p>B. Patient demographic terms</p>	<ul style="list-style-type: none"><li>■ Person descriptors (i.e. white, elderly, female) are not in scope</li></ul>
<p>C. Clinical trial study design terms</p>	<ul style="list-style-type: none"><li>■ Looks like we all agree ...</li></ul>
<p>D. Device failure terms</p>	<ul style="list-style-type: none"><li>■ What level of device failure do we accept?</li></ul>



# What level of device failure do we accept?

- [-] HLT Procedural and device related injuries and complications NEC
  - [+] HLT Anaesthetic complications
  - [+] HLT Cardiac and vascular procedural complications
  - [-] HLT Device failure and malfunction
    - [+] PT Cardiac pacemaker malfunction
    - [+] PT Contact lens discolouration
    - [+] PT Device failure
    - [+] PT Device ineffective
    - [+] PT Dislocation of joint prosthesis
    - [+] PT Extrusion of device
    - [+] PT Failure of implant
    - [+] PT Implantable defibrillator malfunction
    - [+] PT Intra-uterine contraceptive device expelled
    - [+] PT Ventriculoperitoneal shunt malfunction
  - [-] HLT Device related complications
    - [+] PT Complications due to internal joint prosthesis
    - [+] PT Contact lens complication
    - [+] PT Device induced injury
    - [+] PT Device interaction
    - [+] PT Medical device complication
    - [+] PT Medical device discomfort
    - [+] PT Medical device pain
    - [+] PT Neurological complication from device
    - [+] PT Pacemaker complication
    - [+] PT Tooth delamination
  - [+] HLT Endocrine procedural complications

- We have a whole HLT that includes device failures
- ...



# Out of MedDRA ¿? ...

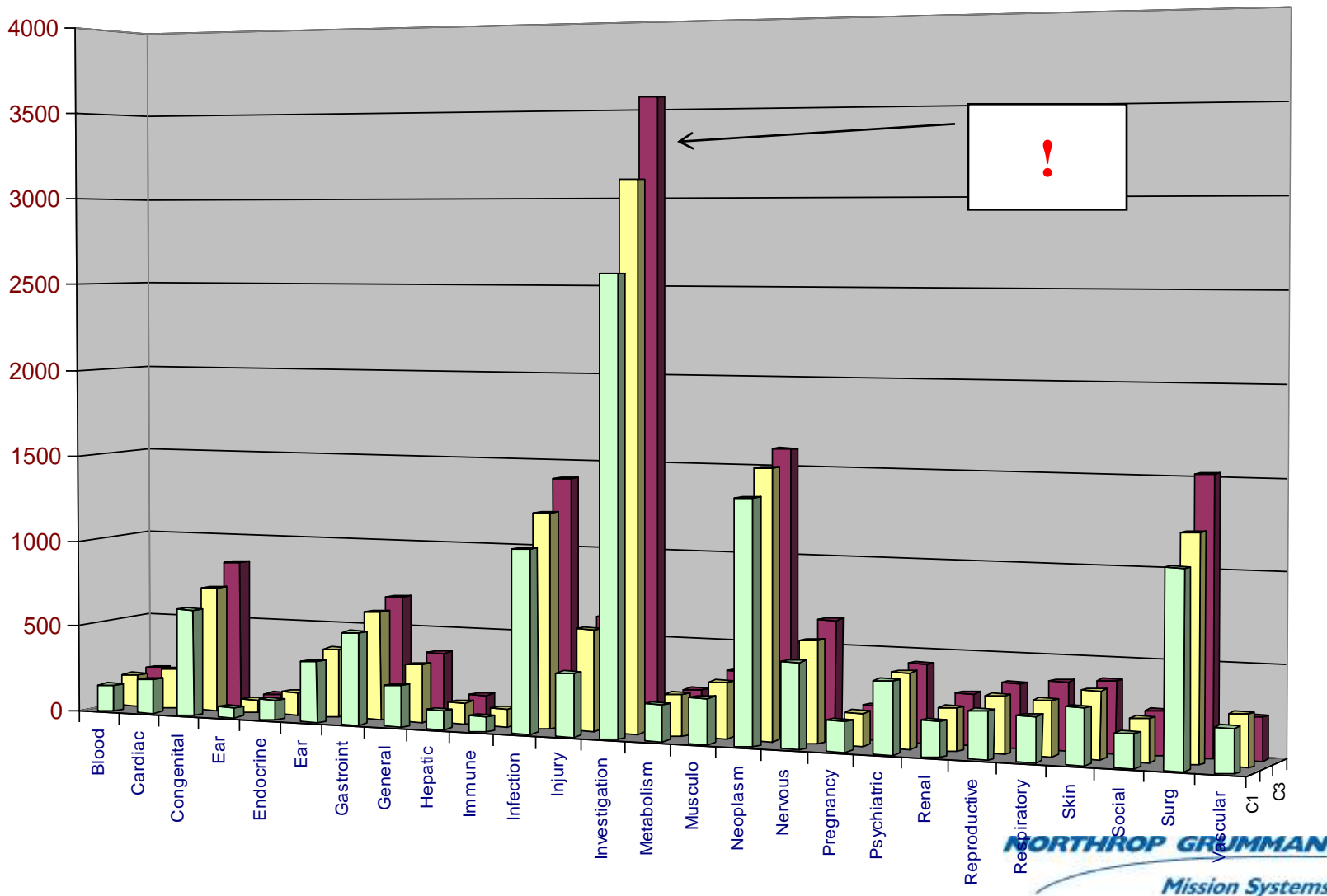
<p>E. Equip, device, diagnostic product terms</p>	<ul style="list-style-type: none"><li>▪ What if they are used frequently and are medically significant? ...</li></ul>
<p>F. Numerical values for results</p>	<ul style="list-style-type: none"><li>▪ Looks like we all agree ...</li></ul>
<p>G. Severity descriptors</p>	<ul style="list-style-type: none"><li>▪ Modified term review has begun and will continue through subsequent versions ... "aggravated," "exacerbated," and "worsened."</li></ul>
<p>H. Population – level qualifiers</p>	<ul style="list-style-type: none"><li>▪ We don t have incidence and prevalence but we have frequency ...</li></ul>



## Other “burning” issues ..

- **“Congenital” and “Acquired”**
- **Demoting NOS to LLT level**
- **Risk Factor Terms**
- **Prophylaxis Terms**
  - **prophylaxis terms should be added if they had marketing approval anywhere in the world**
  - **should be handled as a qualifier ...**

# 2.0 – 4.0 – 5.0 versions distribution



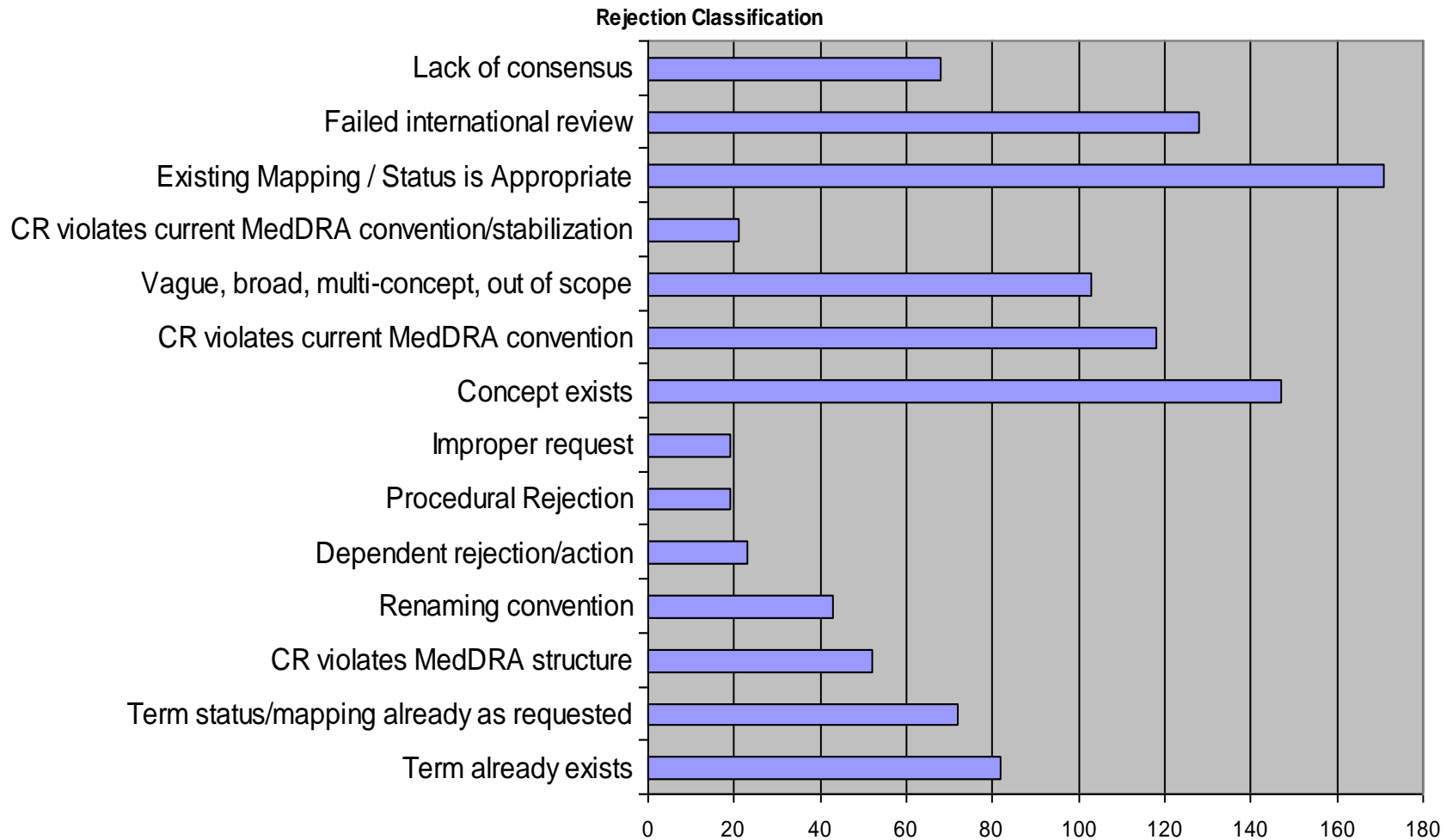


# How specific do we get in Investigations?

Therp. Levels	Sodium valproate level
Hematologic counts	Proerythroblast count (and %)
Serology	<ul style="list-style-type: none"><li>✓ T. Pallidum Hemagglutination &lt; Syphilis test NOS</li><li>✓ Rickettsia typhi IgG</li><li>✓ Parvovirus B19 test</li></ul>
Autoimmune tests	Sjogren's antibody or SSA & SSB
Different means an ratios	<ul style="list-style-type: none"><li>✓ Urine selenium &lt; Blood selenium</li><li>✓ Zinc, hair</li><li>✓ Rheumatoid factor, quantitative</li><li>✓ Total cholesterol/HDL ratio</li></ul>
Classifications	New York Heart Association classification



# Rejection classification





# Colloquialisms – due to terms

- Glare
- Film on the eyes
- Filmy vision
- Cloudy vision
- Hazy vision
- Cardiogenic cerebral embolism
- Atherothrombotic brain infarction
- Cardioembolic cerebral infarction