

# Safety monitoring of ARVs

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# WHO International Drug Monitoring Programme

- Started in 1968 to prevent drug disasters
  - by pooling data from 10 countries with existing spontaneous reporting systems
- Scientific and technical operations moved to Uppsala, Sweden in 1978
  - The WHO Collaborating Centre for International Drug Monitoring (Uppsala Monitoring Centre, UMC) was set up specifically for this purpose
- Vigibase is the data repository
  - Holds pharmacovigilance data from 1968 to date
  - Is managed by the UMC
  - Database now contains 3.9 million individual case safety reports (ICSRs)



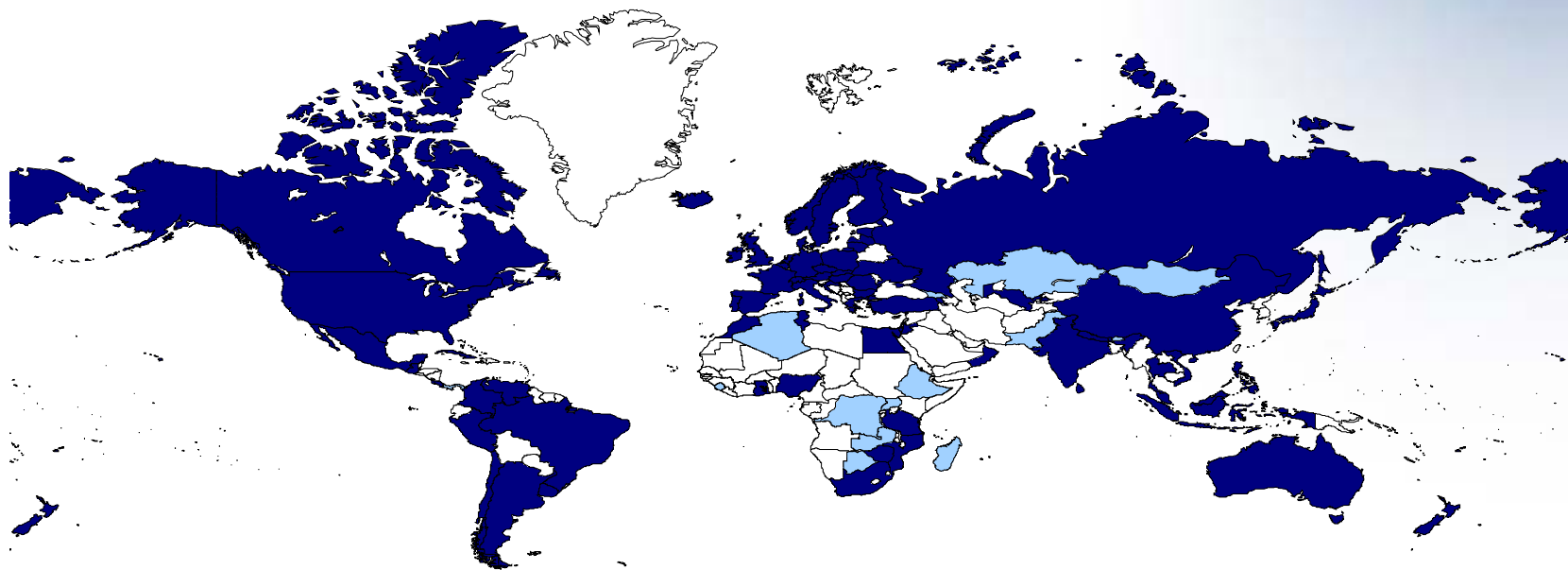
# Uppsala Monitoring Centre

- Runs the scientific and technical operations of the WHO International Drug Monitoring Programme
  - Established as a foundation in Sweden 1978
  - Based on agreement Sweden - WHO
  - International administrative board
  - WHO Headquarters responsible for policy
  - Entirely self-funded
  - No regulatory mandate



# WHO drug monitoring programme

## Participating countries 2007

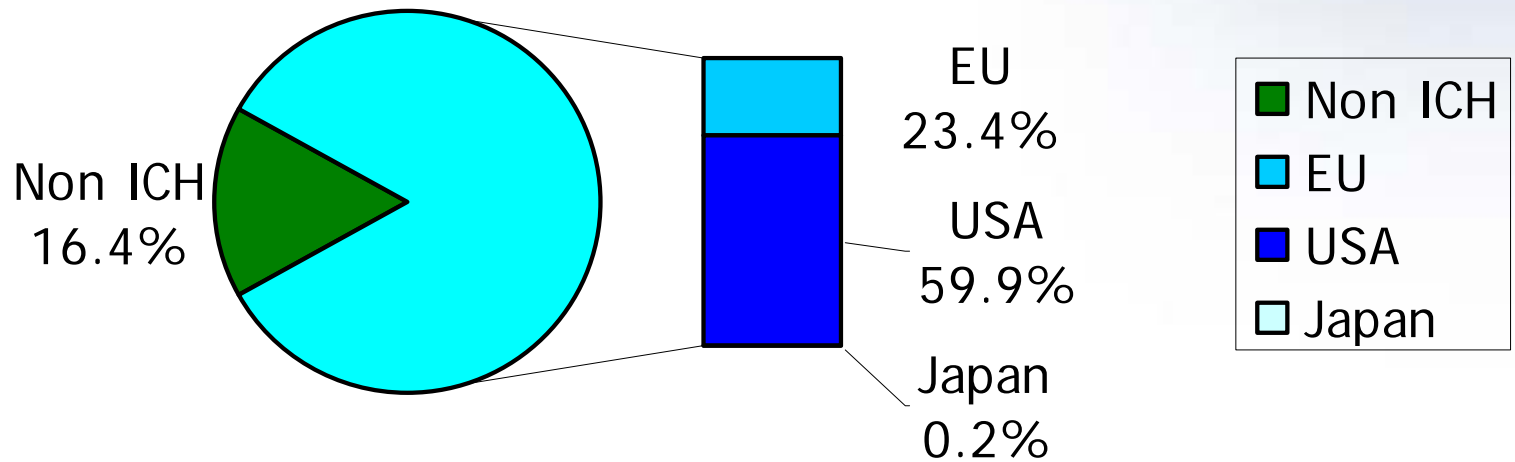


■ Associate member  
■ Member



# Reporting by regions

Data from 2000 - 2005



# Top 15 contributors

Data from  
2000 - 2005

Country	# Reports
USA	953,919
UK	116,105
Canada	65,103
Germany	63,532
Australia	59,499
Thailand	55,560
Netherlands	44,676
Spain	39,441
France	39,256
New Zealand	17,380
Sweden	16,193
Italy	11,777
Switzerland	11,031
Ireland	10,110
Cuba	9,194



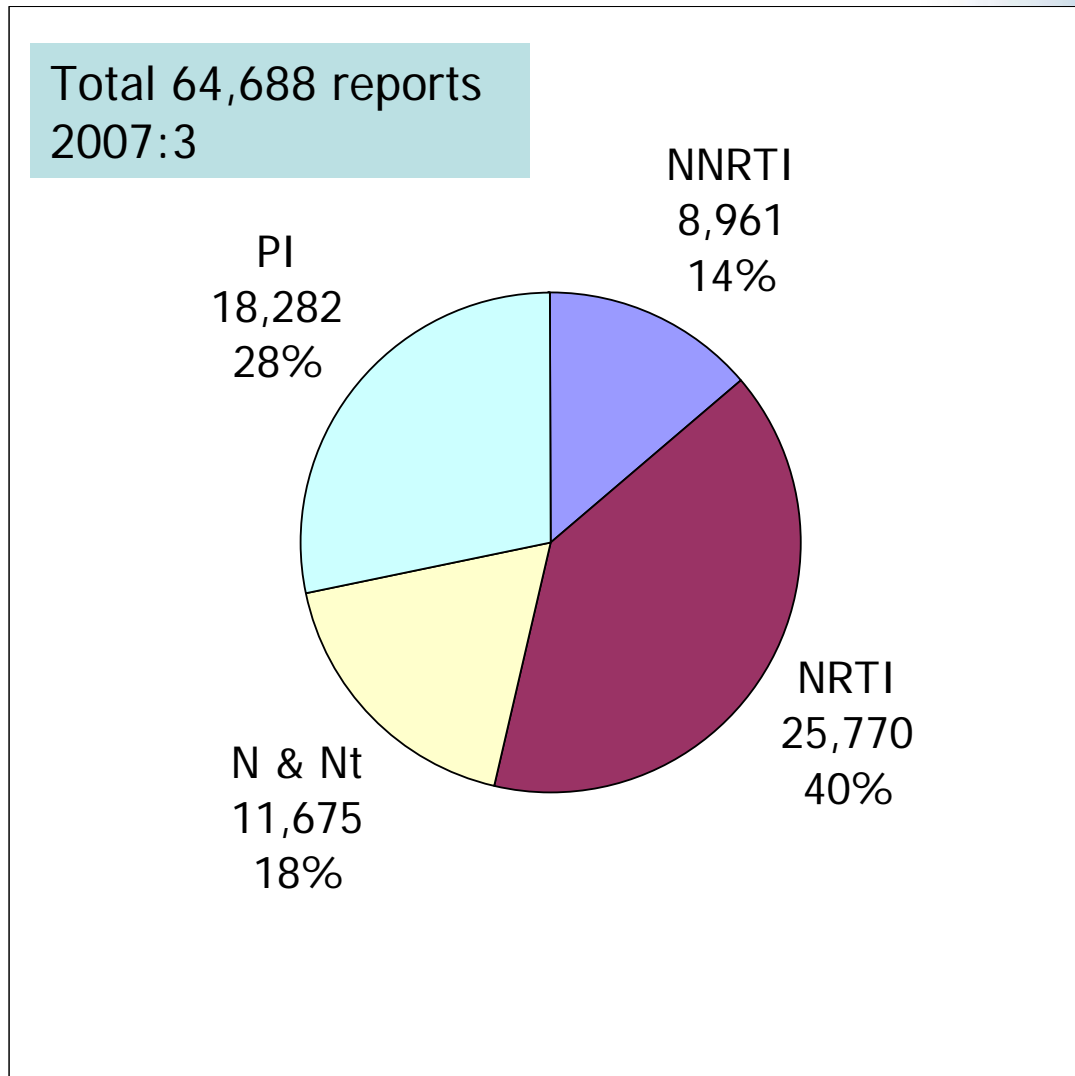
# Top 15 contributors

Data from  
2000 - 2005

Country	# Reps/mill. inhab.	# Reports
New Zealand	717.8	17,380
USA	537.6	953,919
Australia	493.6	59,499
Netherlands	453.8	44,676
Ireland	419.6	10,110
Canada	330.8	65,103
UK	320.2	116,105
Sweden	299.8	16,193
Denmark	249.0	8,117
Switzerland	245.5	11,031
Norway	178.3	4,915
Spain	162.9	39,441
Finland	158.5	4,968
Thailand	141.5	55,560
Cuba	135.0	9,194



# Reporting of ARVs in Vigibase





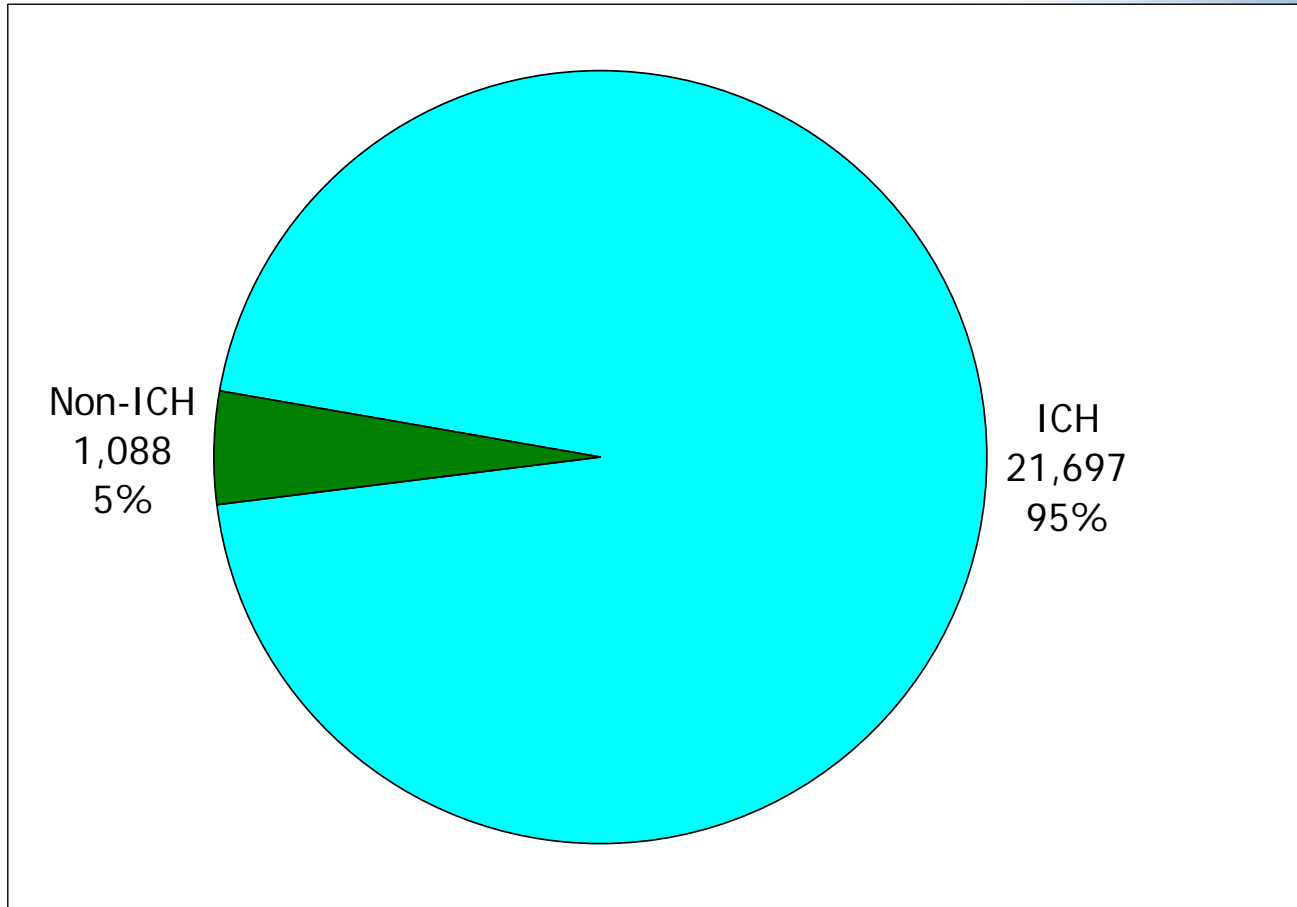
# Top ten reported ARVs

<b>INN</b>	<b># reports</b>	<b>Class</b>
Indinavir	6369	PI
Aciclovir	6267	N & NT
Lamivudine	5597	NRTI
Stavudine	5526	NRTI
Zidovudine	4766	NRTI
Efavirenz	4561	NON-NRTI
Didanosine	4154	NRTI
Nevirapine	4094	NON-NRTI
Ritonavir	4004	PI
Abacavir	3052	NRTI



# Regional distribution of ARV reports

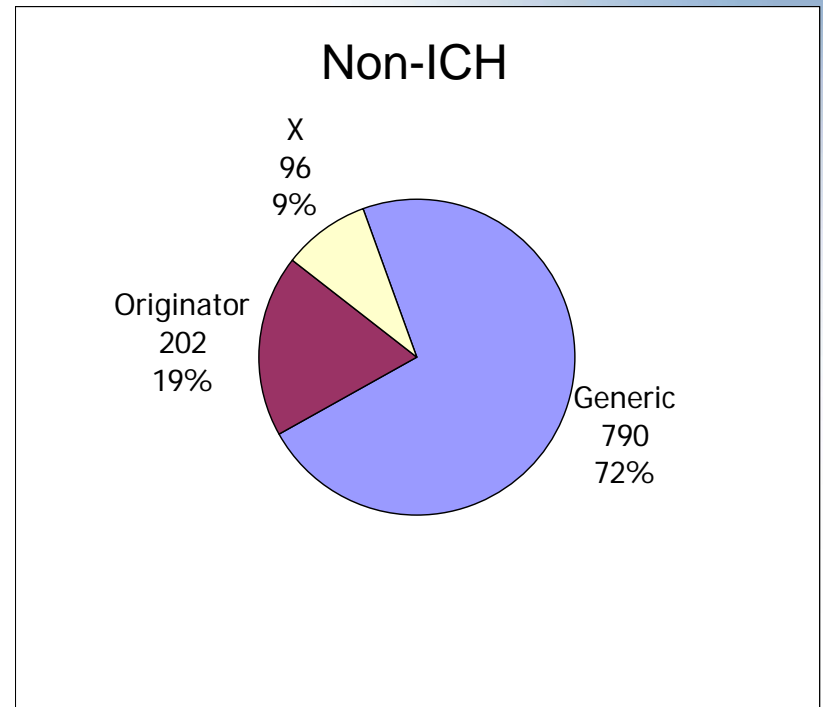
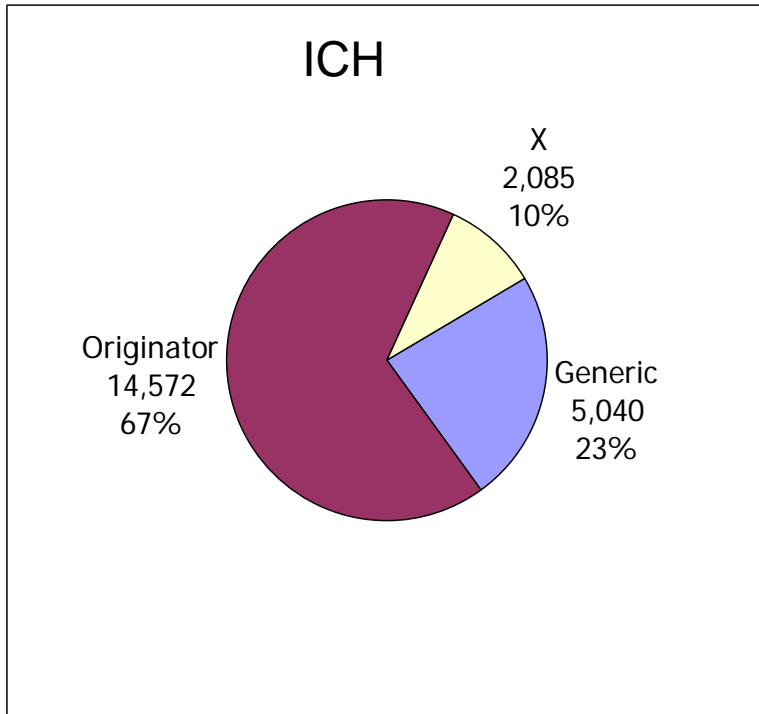
Data from a study made by UMC in 2007 covering  
INNs included in PQP programme, report year 2001-2005



ICH= EU, US, JP + NZ,AUS,CAN



# ARV reports by product category



# Some more results

- 1138 different reaction terms reported
  - 900/1138 in ICH countries only
  - 8/1138 in non-ICH countries only
- General, metabolic and G-I reactions common for all three product categories
  - also most common in ICH countries
  - Skin and G-I reactions most common in non-ICH countries



# Conclusion

- Reported safety profiles of ARVs differ between the richer countries and those with limited resources
- Is this due to higher under-reporting in non-ICH countries, or much lower availability of ARVs, or differences in adverse reaction responses?
- WE NEED TO FIND OUT!



# What the UMC can contribute

- 30 years experience in safety monitoring
- Web based reporting tool (VigiFlow)
  - local - regional - central access levels
  - built in terminologies for drugs and events
  - can be adapted for Cohort Event Monitoring
- Database management system and screening and analysis methods that can handle large amounts of data

