

When do clinicians usually extrapolate in their practice?

Daniel Brasseur

CHMP

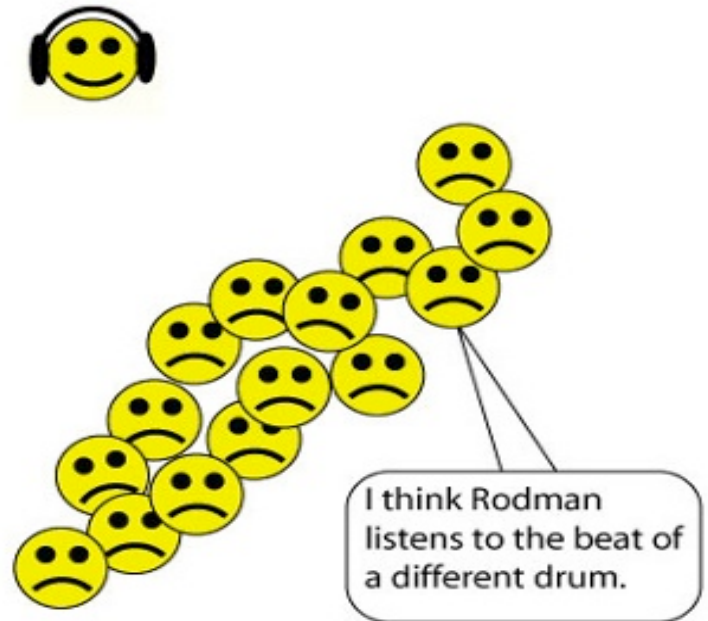
Christoph Male

PDCO

Frequent approaches in the Clinical setting

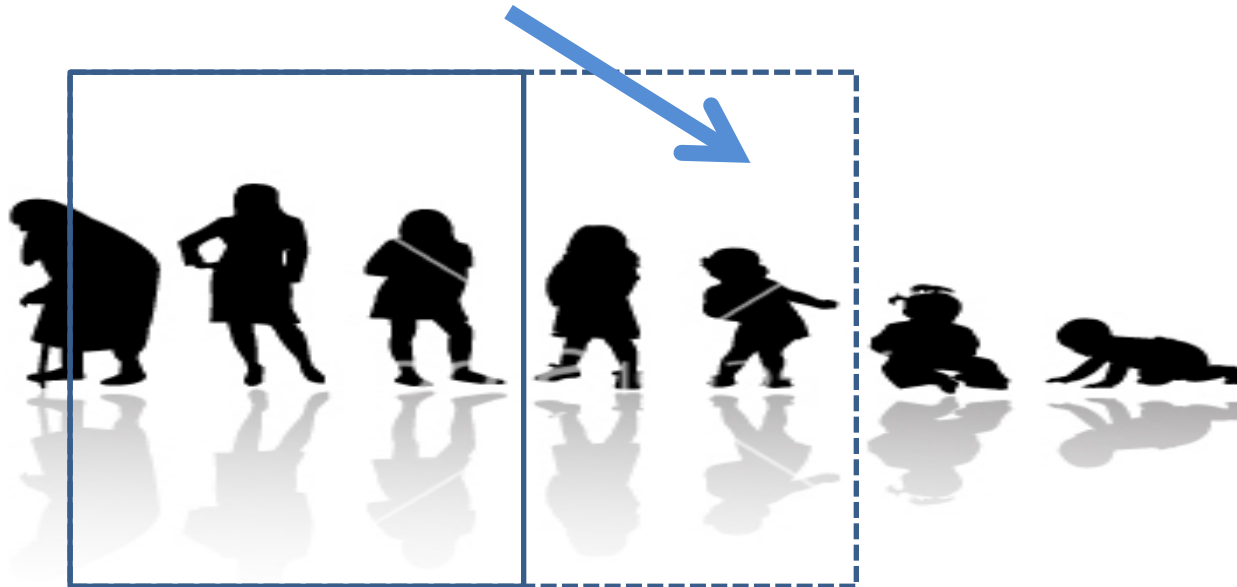
Extrapolation across

- **Patients**
- Products
- Pathologies



Patients

Same medicine than in adults used
'down the age'



Report published on the uses of medicines for children in the European Union

YES

Report published on the uses of medicines for children in the European Union

1 - A report on the survey of all uses of medicines for children in the European Union was published today. The report is a key deliverable of the European Commission's Regulation (EC) No 1901/2006 which aims to improve the quality of medicines for children in the European Union.

The results show that the prescription of off-label medicines (i.e. medicines used outside their marketing authorisation) and unauthorised medicines are widespread in Europe.

The therapeutic classes that are used most frequently without a marketing authorisation are:

- ▶ anti-arrhythmics;
- ▶ antihypertensives (renin-angiotensin inhibitors and beta-blockers);
- ▶ proton-pump inhibitors and H2-receptor antagonists;
- ▶ anti-asthmatics;
- ▶ antidepressants (mainly selective serotonin re-uptake inhibitors, serotonin-norepinephrine re-uptake inhibitors and tricyclic antidepressants);
- ▶ contraceptives (in adolescents);
- ▶ antibiotics (in very young children).

The results of the survey will support the work of the Paediatric Committee (PDCO) when it develops its next inventory of paediatric needs. This is a list which describes the different therapeutic areas where research into and development of medicines for children is especially needed. This applies to both old (off-patent) or new medicines (including authorised medicines and those under development).

Related information

Report on the survey of all uses of medicines for children in the European Union: Executive summary (20/01/2011)

Report on the survey of all paediatric uses of medicinal products in Europe: Questions and answers (20/01/2011)

Report on the survey of all paediatric uses of medicinal products in Europe (20/01/2011)

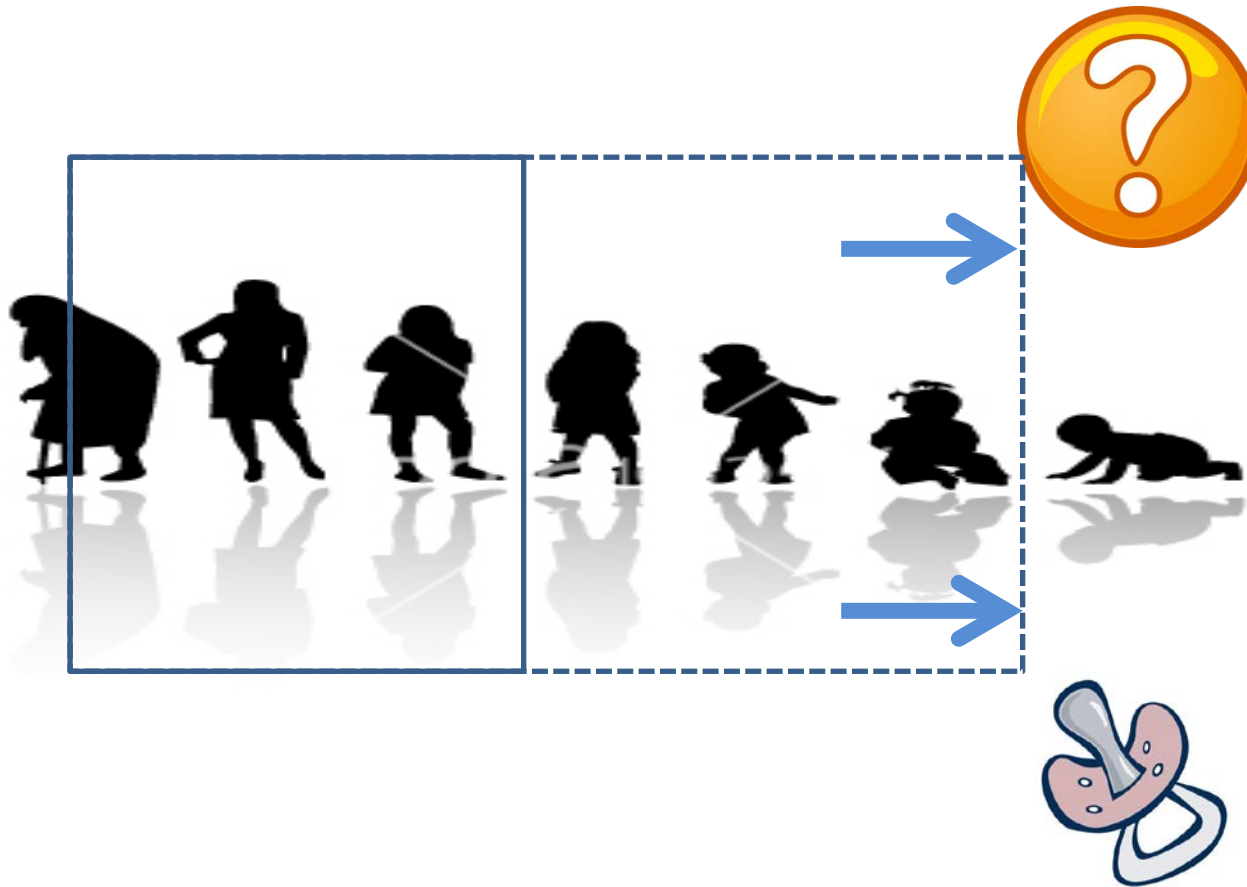
Contact point:

inventory@ema.europa.eu

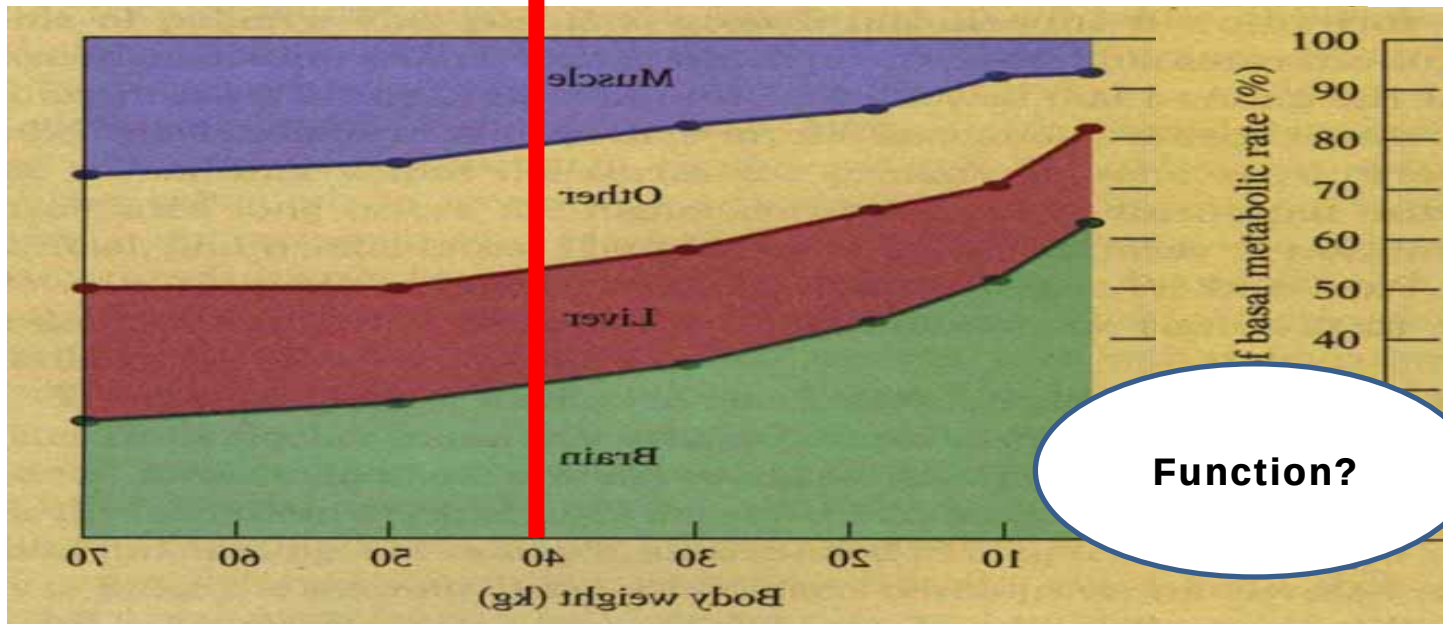
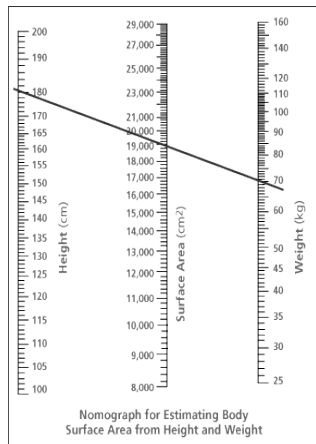
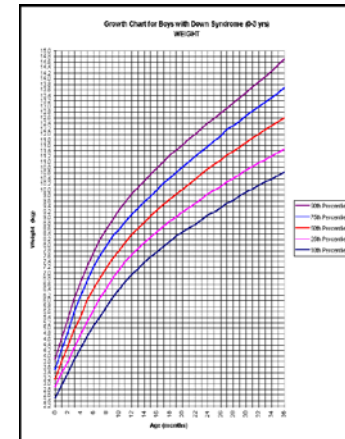
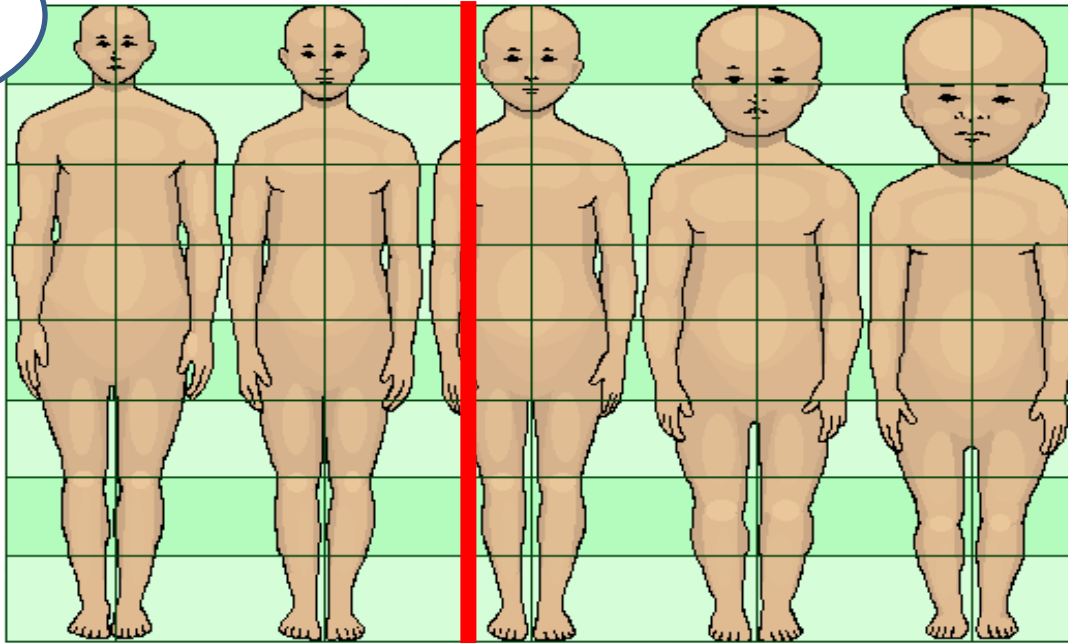
Off-label use

Patients

'down the age'
How Far can we go ?



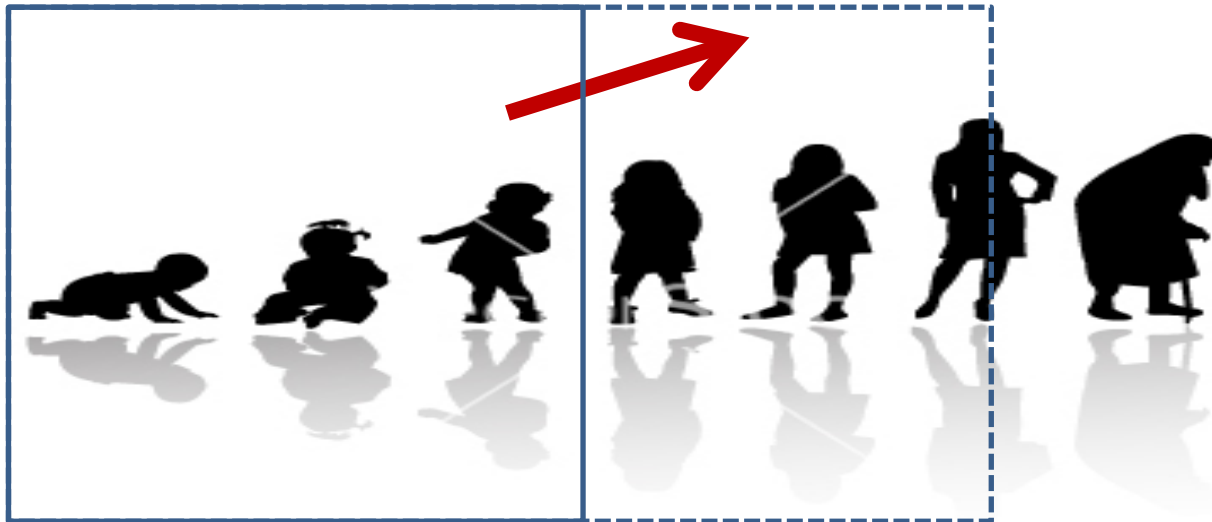
Morphology?



Function?

Patients

‘Up the age’

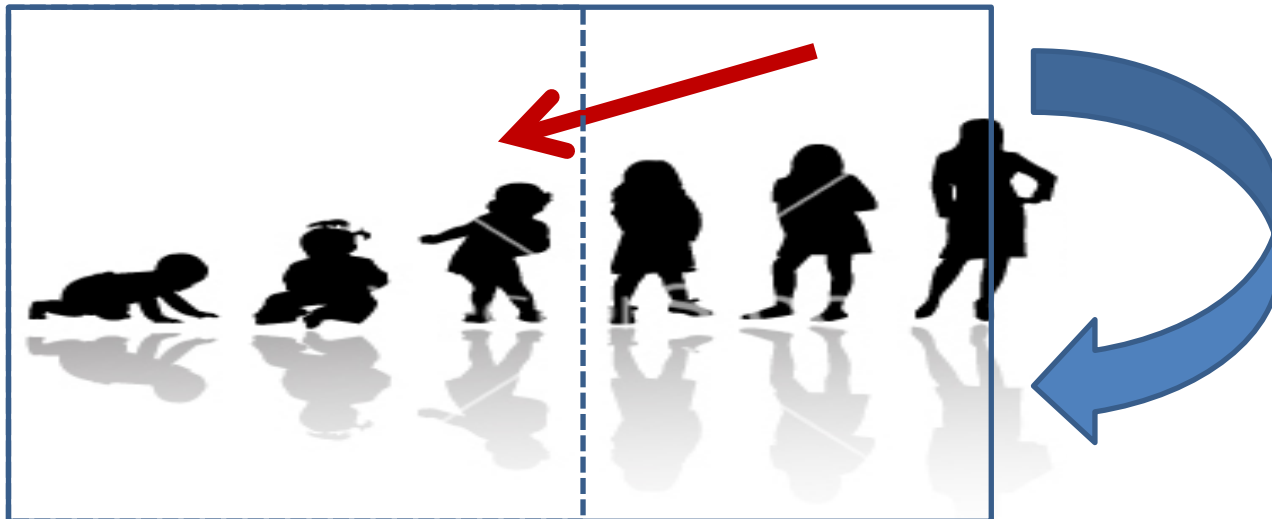


**Cystic fibrosis
Congenital disorders
(orphan conditions)**

...

Patients

‘Up and down again...’



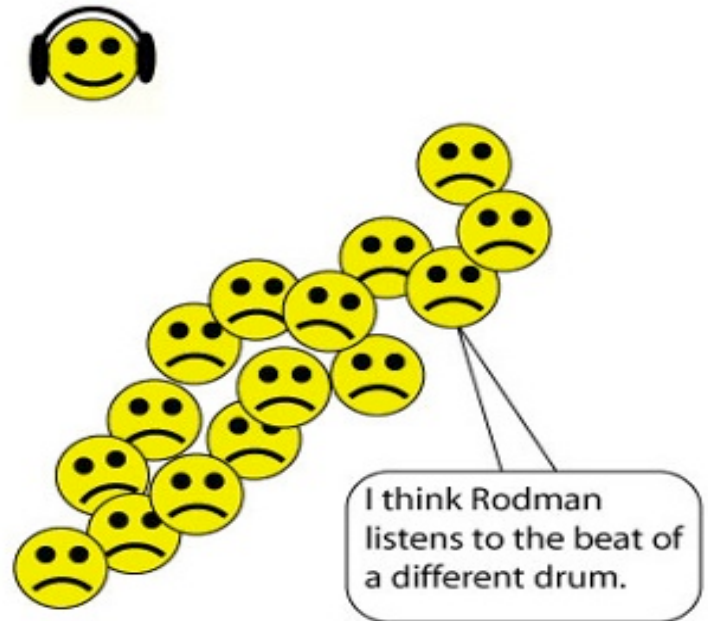
**Cystic fibrosis
Congenital disorders
(orphan conditions)**

...

Frequent approaches in the Clinical setting

Extrapolation across

- Patients
- **Products**
- Pathologies



Products

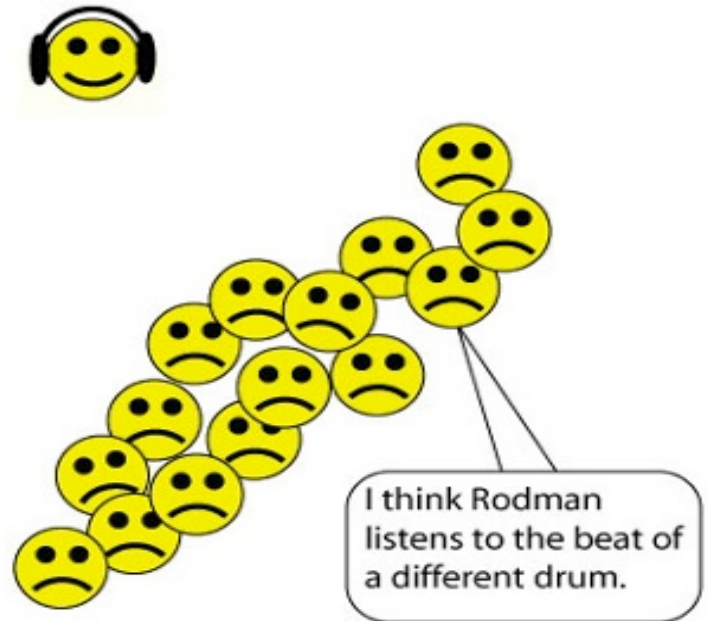
Different medicines belonging to a class

- **Drug / pro-drug**
([des] loratadine...)
- **Bio-equivalence**
(Release formulation, conversion factor)
- **Therapeutic equivalence**
(anti-TNF in MS, Blood factor substitution, ERT)
(vaccines, based on sero-conversion factors)
(one statine to another, monitored by LDL-Chol))
- **Me-too, is not equi-potency**
(for E [long term effect statines]& / or S...)

Frequent approaches in the Clinical setting

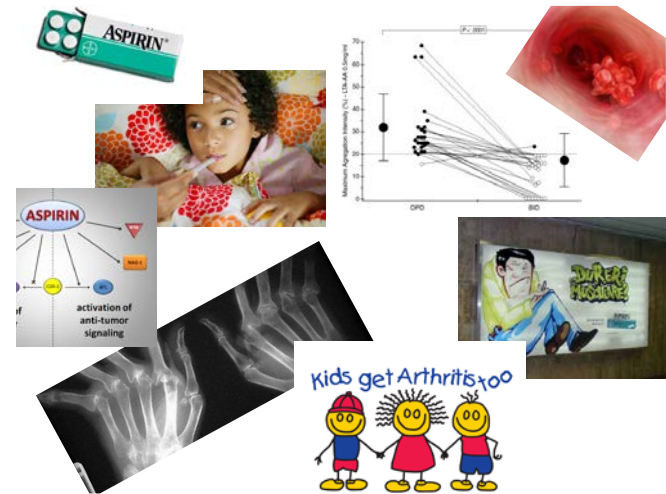
Extrapolation across

- Patients
- Products
- **Pathologies**



Same products used for different diseases

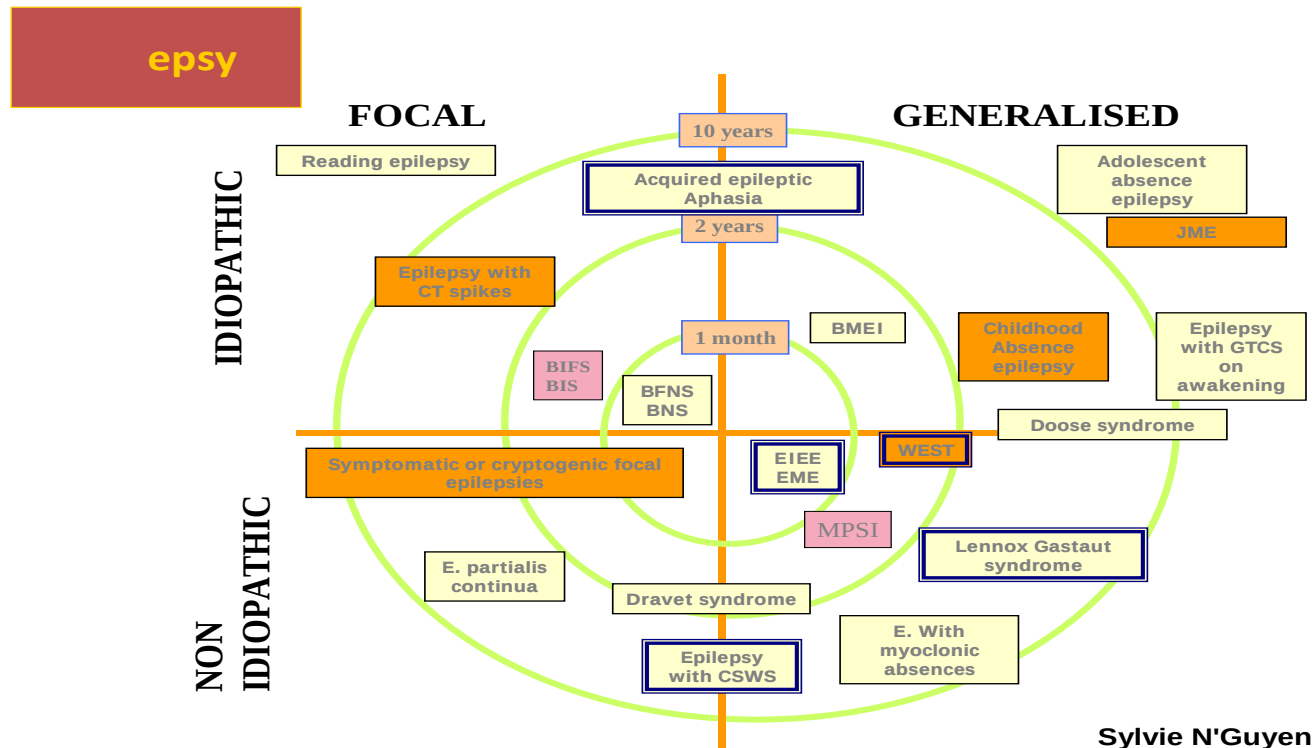
- pain / fever
- leukaemia / lymphoma
- arthritis...
- HTA [primary,secondary] / heart failure
- Allergy / exercise induced asthma
- Heart failure stage I,II,III,IV
- Cancer stage, relapse...



Pathologies

Pathologies

Same product but used in different diseases



Sylvie N'Guyen

How do Clinicians behave?

Interlinking

- **Mechanism of action of the disease (pathogenesis / pathways)**
- **Mechanism of action of the drug (target, receptors)**
- **Clinical condition / presentation (individual sign & symptoms)**

