

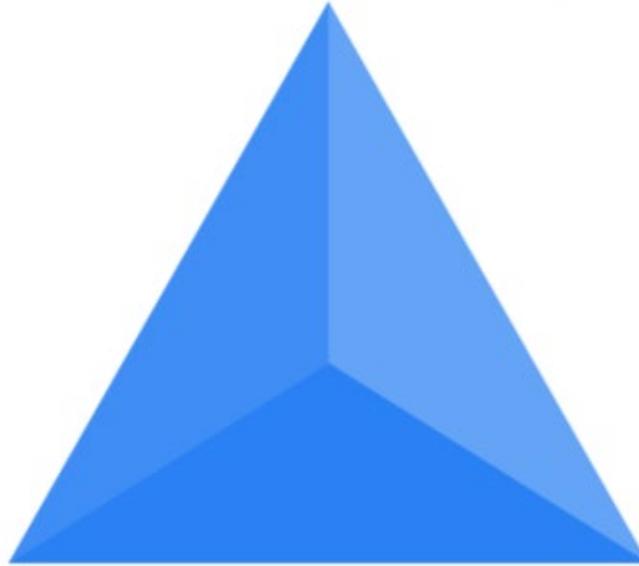
# Modelling and Simulation in Drug Development and Assessment

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**Computations to  
support drug  
development,  
monitoring and use**



**DATA**

**IMPACT**





Computations to  
support drug  
development,  
monitoring and use

## What is M&S?

Integration and  
analysis methods for  
data of different types  
and from different  
sources





Computations to  
support drug  
development,  
monitoring and use

PBBM  
PBPK/QSP  
POPPK/PKPD  
E-R

What is  
M&S?





Computations to  
support drug  
development,  
monitoring and use

Data for  
M&S?

Quality and CMC data  
In vitro and in vivo  
nonclinical and  
clinical data



Computations to support drug development, monitoring and use

Streamlining of manufacturing processes  
Implementation of 3Rs

Impact of M&S?





**Computations to  
support drug  
development,  
monitoring and use**

## **What is M&S?**

**Analytical and  
Decision tools to  
support drug and  
trial approvals**





Computations to  
support drug  
development,  
monitoring and use

## What is M&S?

- Pharmacological models (PK/PD)
- Biostatistical models (e.g. Bayesian models)





**Computations to  
support drug  
development,  
monitoring and use**

**Data for  
M&S?**

**(Non)Clinical trial  
data**



Computations to support drug development, monitoring and use



## Impact of M&S?

Optimization of clinical evaluation of drug





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## **What is M&S?**

**Descriptors of  
disease trajectories  
and drug's behaviour**



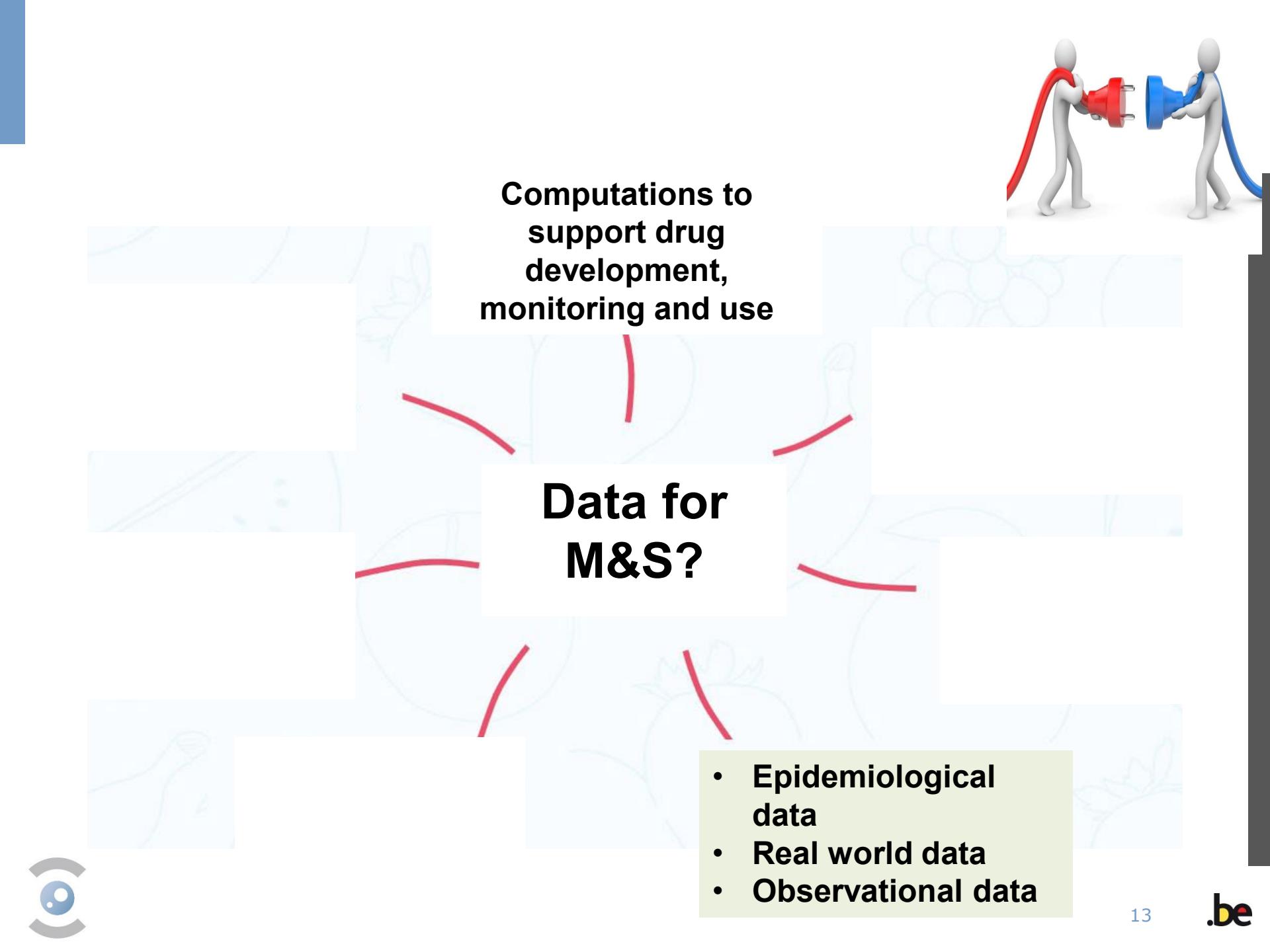


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## What is M&S?

- Disease progression models
- Epidemiological models





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## **Data for M&S?**

- Epidemiological data
- Real world data
- Observational data



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## Impact of M&S?

Disease/outbreak monitoring and management





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## **What is M&S?**

**Predictors of  
long- and short-  
term outcomes  
of trials**





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## **What is M&S?**

**Disease and  
Drug effects  
models  
Clinical Trial  
Simulations**





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development,  
monitoring and use**

**Data for  
M&S?**

**Clinical  
Littérature  
Synthetic  
eHealth data**





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# What Is Data?

Optimization of implementation clinical trials





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development,  
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## What is M&S?

Extrapolation  
models  
(e.g. for paediatric  
and rare diseases)





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## **What is M&S?**

**Predictors of  
treatment outcomes  
in different (sub-)  
populations**





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development,  
monitoring and use**

**Data for  
M&S?**

- Cross-diseases
- Cross populations
- Cross drugs data



Computations to support drug development, monitoring and use



improved access to high quality treatment for small populations

Impact of M&S?



**Powerful tools** for  
drug development,  
use and  
postmarketing  
monitoring

**Computations to  
support drug  
development,  
monitoring and use**

**What is  
M&S?**





Computations to  
support drug  
development, Use and  
monitoring

- AI/ML
- Digital twins
- Integration of different types of models

What is  
M&S?





All relevant data  
needed to address the  
Question of Interest

Integration of  
different types  
of data

Impact of  
M&S?





Most of Drug  
development and use  
Question can be  
addressed with M&S

- Given this High impact,  
It crucial to ensure the  
High quality of M&S tools
  - Model evaluation  
is key**

Impact of  
M&S?



# Contact

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