

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**

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

**What is
M&S?**



**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**

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

**Data for
M&S?**



**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**





**Computations to
support drug
development,
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**What is
M&S?**

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





**Computations to
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development,
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What is M&S?

- **Disease progression models**
- **Epidemiological models**





**Computations to
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Data for M&S?

- **Epidemiological data**
- **Real world data**
- **Observational data**

**Computations to
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**Impact of
M&S?**

**Disease/outbreak
monitoring and
management**





**Computations to
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**What is
M&S?**

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





**Computations to
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development,
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**What is
M&S?**

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





**Computations to
support drug
development,
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**Data for
M&S?**

**Clinical
Littérature
Synthetic
eHealth data**





**Computations to
support drug
development,
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What Is Data?

**Optimization of
implementation
clinical trials**





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

**What is
M&S?**

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





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

**What is
M&S?**

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





**Computations to
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Data for M&S?

- **Cross-diseases**
- **Cross populations**
- **Cross drugs data**





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

**Impact of
M&S?**

**improved access to
high quality
treatment for small
populations**





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

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

**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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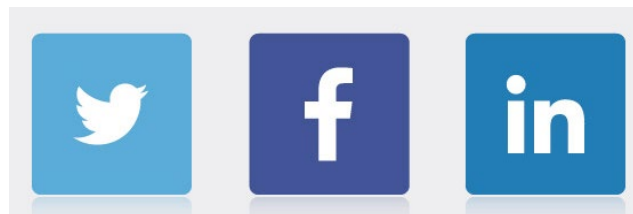
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A large, stylized graphic of a human eye in the background. The eye is composed of a light blue iris with a white pupil, and a grey arc representing the upper eyelid. The entire graphic is semi-transparent.

**Your medicines and health products,
our concern**