ONCOLOGY CONFERENCE

Pharmaceutical Development

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#Oncology2020

Confidential

Biopharmaceutics in Complex Parenteral Formulation Design

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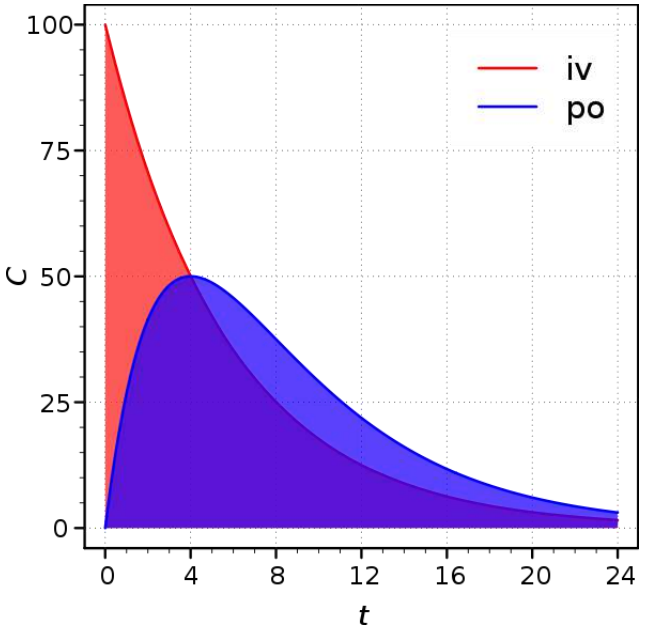
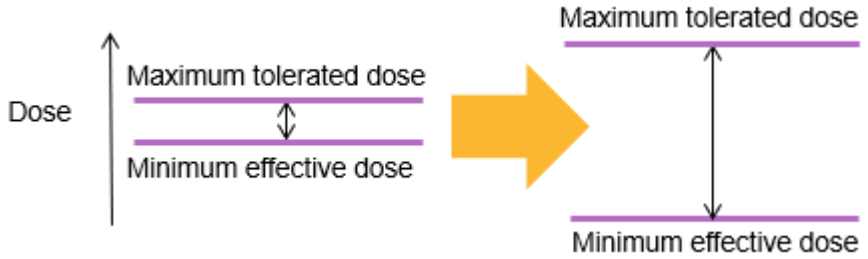
Patient Centric Formulation Design

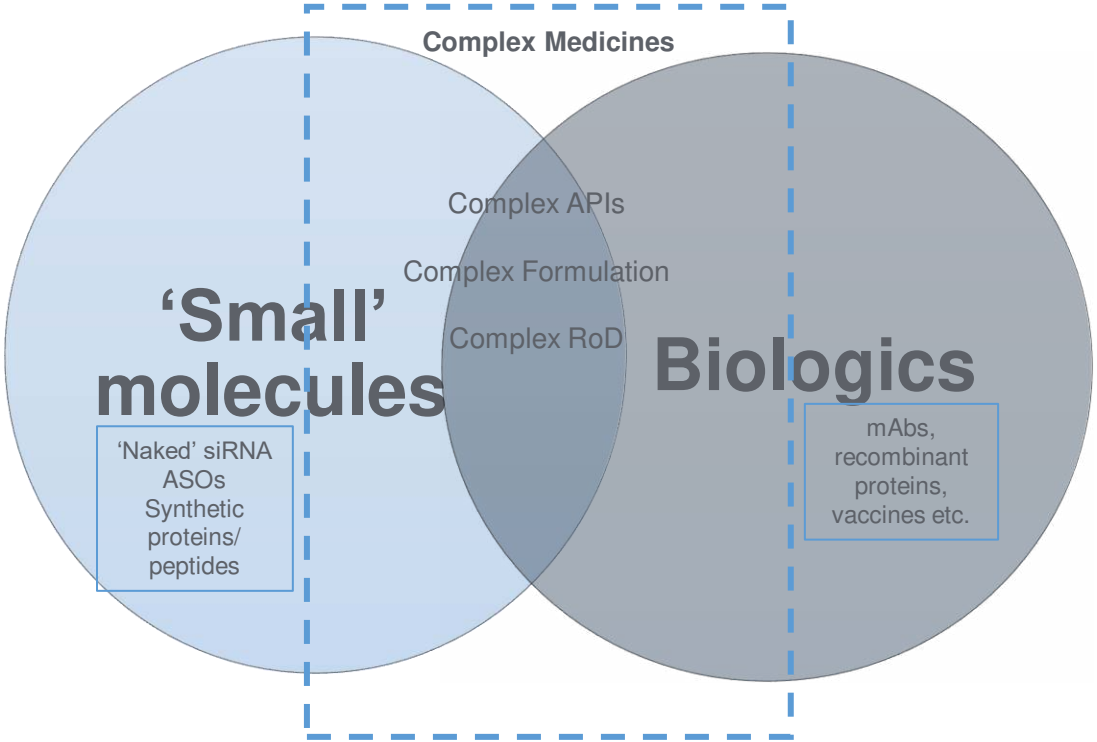


Traditional PK



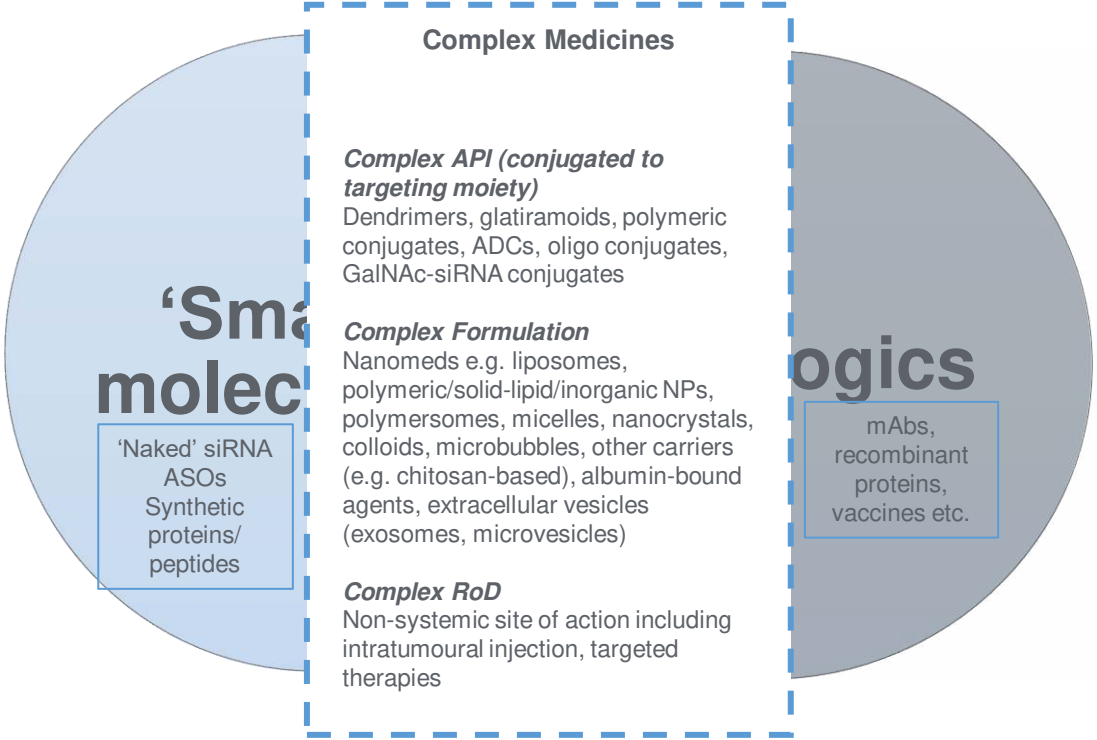
Optimise PK and Biodistribution to Maximise Therapeutic Index

Complex Medicines in Oncology



RoD = route of delivery
ASOs = Antisense oligonucleotides
siRNA = small interfering RNA
ADCs = antibody-drug conjugates

Complex Medicines in Oncology



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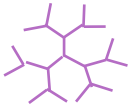
Nanomedicines

Drug-
Polymer
Conjugates



Dendrimers

Antibody Drug Conjugates

Drug chemically linked
to a carrier

Micelles

Liposomes

Polymeric
nanoparticles

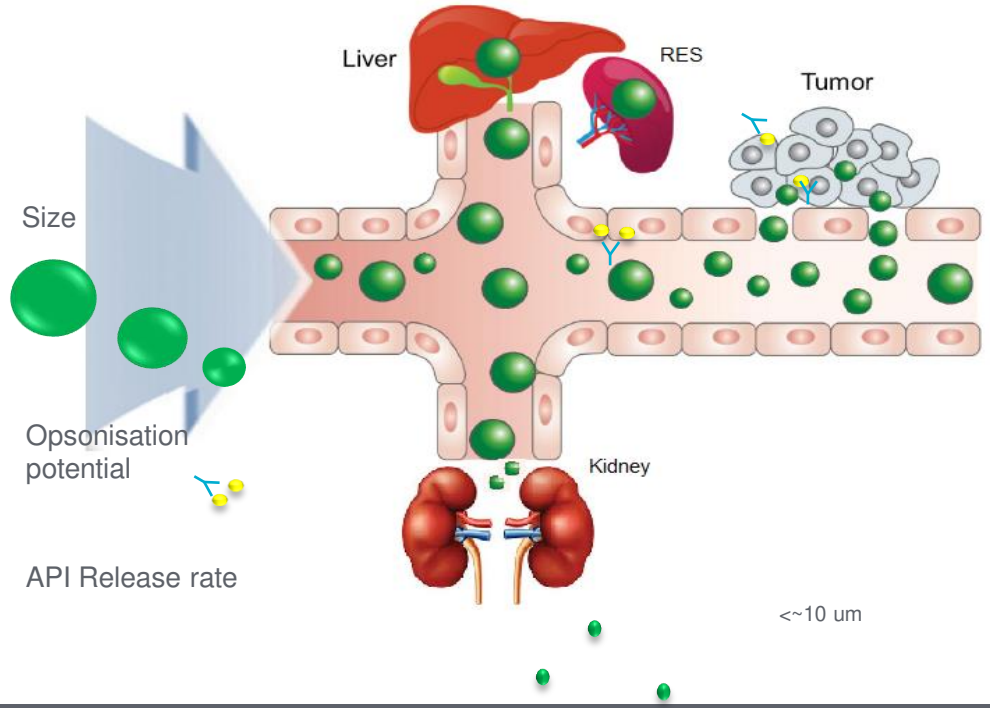
Inorganic
nanoparticles

Lipid
nanoparticles

Polymersomes

Drug encapsulated in
a carrier

Nanoparticles for Biophysical Targeting: Critical Quality Attributes



Subcutaneous Injection: Patient and Clinical Perspective

Patients Prefer Subcutaneous Trastuzumab Administration in HER2-Positive Metastatic Breast Cancer

European Journal of Cancer

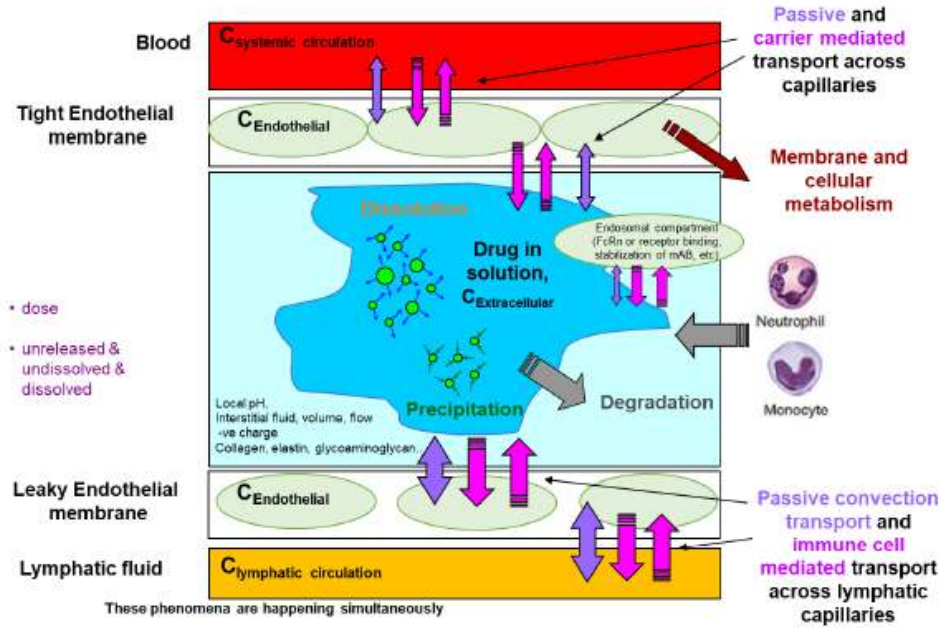
TAKE-HOME MESSAGE

- This randomized study was designed to evaluate patients' preference of subcutaneous or intravenous trastuzumab for the management of metastatic, HER2-positive breast cancer. The subcutaneous formulation was preferred by 85.9% of patients vs 14.1% who preferred the intravenous formulation ($P < 0.001$). Toxicity was consistent with the known safety profile.
- The definitive preference for subcutaneous trastuzumab is consistent with what has been previously reported in patients with early-stage breast cancer.

– Neil Majithia, MD

+	-
Patient convenience – less chair time	Bleeding risk in patients with low platelet counts
Less time and manipulation from Pharmacy	Sites of admin need to be rotated
Less nurse administration time – i.e more patients treated	Max injection volume is limited to ~2ml, multiple injections per dose may be required
Potential for home administration	Injection site reactions/allergic reaction
Potential for improved safety profile	

SC Absorption Processes (mAbs)



M. Sánchez-Félix, M. Burke, H.H. Chen, et al., Predicting bioavailability of monoclonal antibodies after subcutaneousadministration: Open innovati..., Adv. Drug Deliv. Rev.

Biopharmaceutics Challenges

- Biopharm tools for SC formulations are in their infancy compared with oral delivery
- Preclinical to clinical and cross species translation of SC bioavailability/absorption rate is poor
- In vitro release models are often non compendial, lack guidance, poorly predictive
- In vitro in vivo correlation is challenging

Active research efforts ongoing to develop novel biorelevant in vitro methods and mechanistic in silico models to improve IVIVR and enable smarter formulation and in-vivo study design

Questions?