Université de Montréal

CRS IPEC Americas Summit

Overview of administration of biologics

Simon Matoori, PhD

Professor, Université de Montréal

Chair, CRS Focus Group Skin & Mucosal Delivery

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Agenda: Morning session (I)

Introductory talks

8:30 AM & 8:35 AM

Welcome, Logistics, Intro & Overview of administration of biologics: past, present, future

Simon Matoori, Université de Montréal

8:35 AM

Biologics Summit Part 1 review and key learnings

Nigel Langley, Gaylord Chemical & IPEC-Americas

9:05 AM

Introduction to high dose/high volume SC administration of biologics and the SC Delivery Consortium

Beate Bittner, F. Hoffmann - La Roche Ltd

Agenda: Morning session (II)

New technologies in high dose/high volume SC delivery

9:30 AM
Crash Course on High Dose/High Volume Subcutaneous Delivery with Recombinant Human Hyaluronidase (rHuPH20)
Marie Printz, Halozyme

10:20 AM
Microglassification™ suspensions of biologics for SC delivery of high concentration formulations
Deborah Bitterfield, Lindy Biosciences

10:50 AM
An injectable hydrogel particle platform enabling high concentration delivery of amorphous solid and crystalline biologics
Patrick Doyle, MIT

11:20 AM
XERIJECT formulation technology for SC delivery of ultra-high concentration biologics
Rick Fitch, Xeris Pharmaceuticals

Agenda: afternoon session

Predicting SC bioavailability

1:00 PM
Prediction of clinical SC bioavailability: relevance of in vivo models
Beate Bittner, F. Hoffman - La Roche

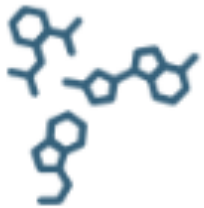
1:30 PM
How Aggregated Clinical Data Can Provide Greater Utility than Animal Models for Predicting Antibody Subcutaneous PK
Ryan Nolan, Halozyme

2:00 PM
Uncloaking In-vitro Subcutaneous Bioavailability Tools
Manuel Sanchez-Felix, Novartis

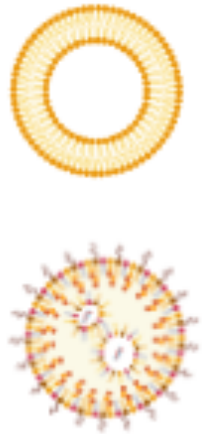
2:30 PM
Predicting Subcutaneous Drug Absorption via Machine Learning Attempts and A Custom In Vitro Device
Hao Lou, University of Kansas

3:15 PM & 4:00 PM
Panel Discussion & Conclusion
Simon Matoori, Université de Montréal

Therapeutic modalities

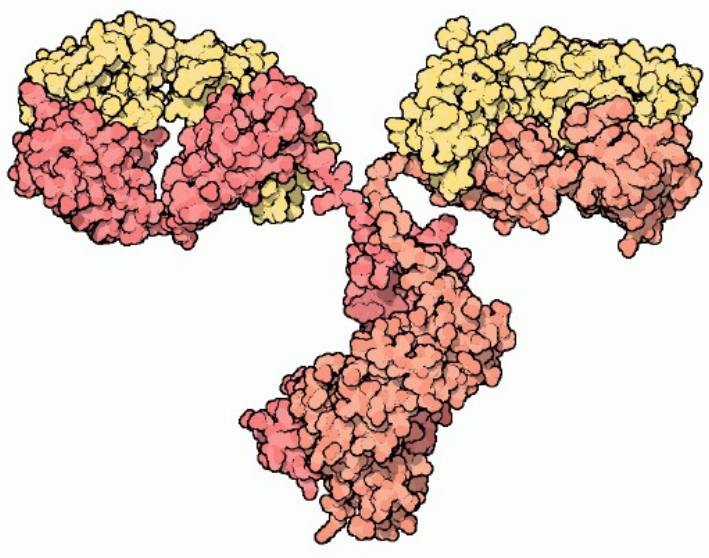




Antibody

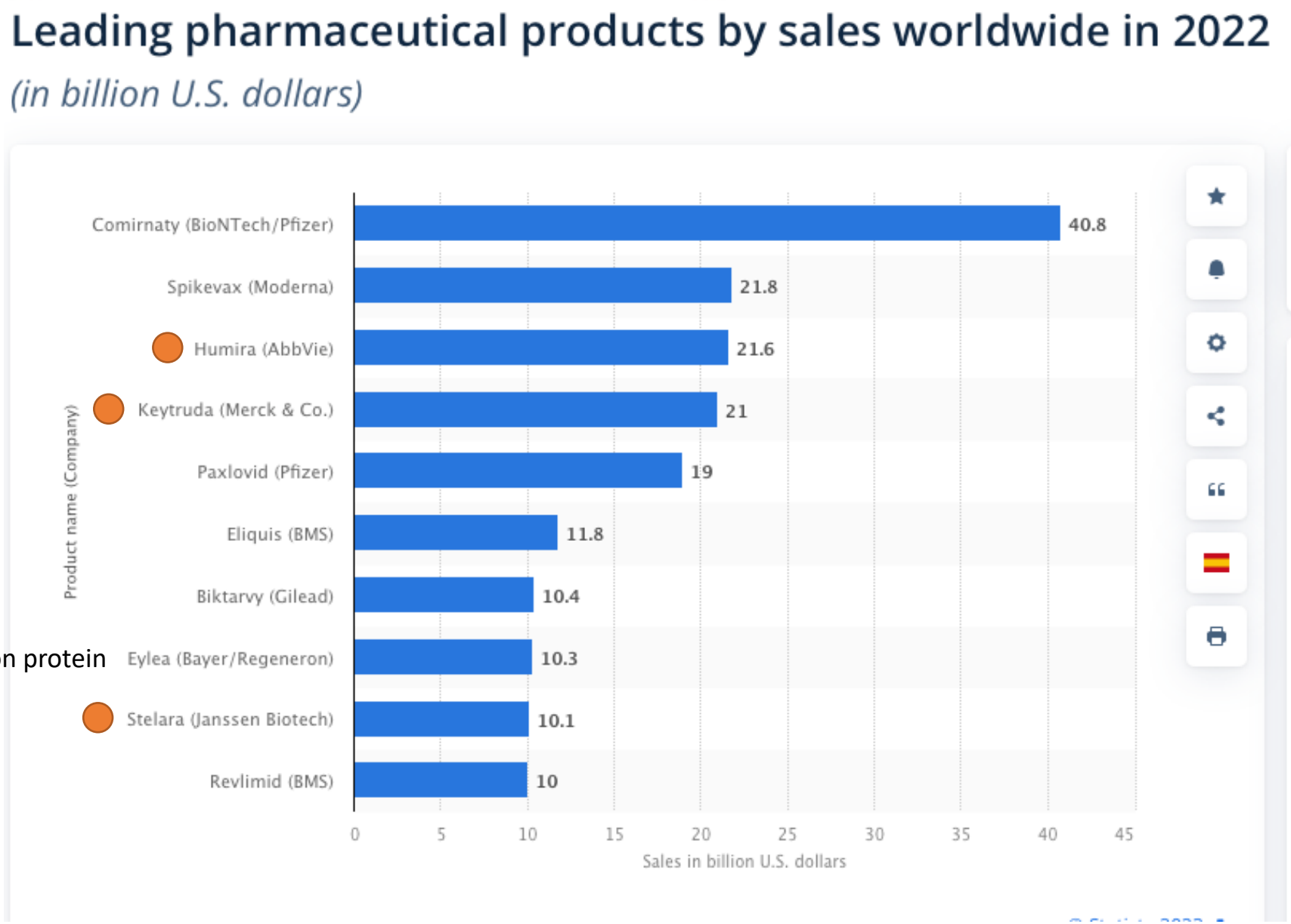
- Made of amino acids
- Glycation
- Highly charged
- High molecular weight (ca. 150 kDa)



- High affinity to epitope
  - Mono- or bispecific
- Can be covalently coupled to low Mw drugs (antibody-drug conjugate)
- Antibody fragments
- Currently over 100 FDA-approved monoclonal antibodies

Ryman & Meibohm CPT Pharmacometrics Syst Pharmacol 2017
Lyu et al. Antib Ther 2022

Most sold pharmaceuticals 2022



Fusion protein

Statista

Routes of administration

Parenteral route

Intravenous
Intramuscular
Subcutaneous
Intradermal
Intrathecal
Intraarticular
Intraperitoneal

Enteral route

Oral
Sublingual
Buccal
Rectal

Topical route

Transdermal
Nasal
Pulmonal

Ruiz & Montoto ADME Processes in Pharmaceutical Sciences 2018

Most sold pharmaceuticals 2022

SC

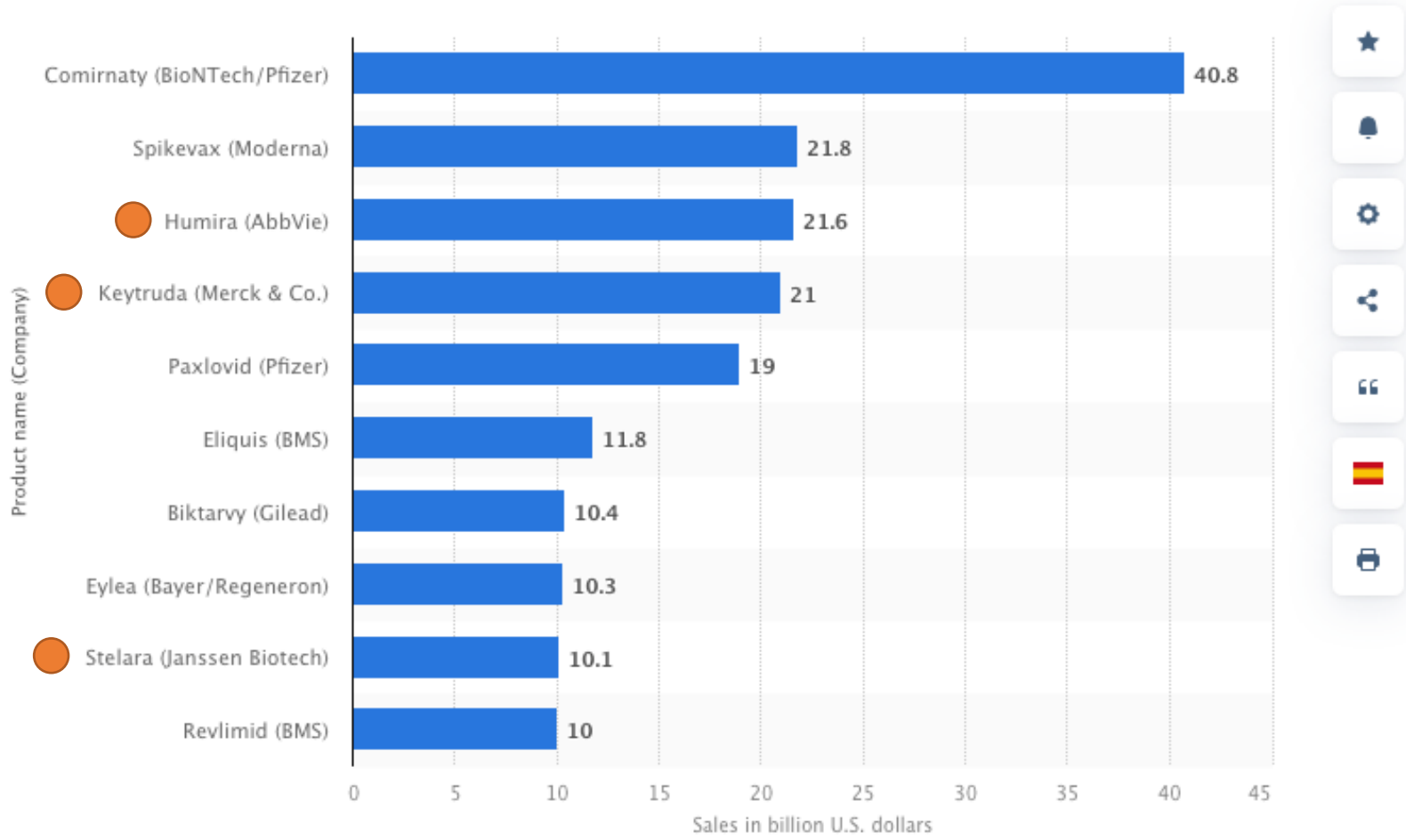
iv

SC

SC

Leading pharmaceutical products by sales worldwide in 2022

(in billion U.S. dollars)



Statista

Parenteral route

	Intravenous	Intramuscular	Subcutaneous
	Peripheral veins	Muscles (deltoid, triceps)	Abdomen, legs, arms
Invasiveness	High	High	Low
Self-administration	Not possible	Not possible	Possible
Bioavailability	High	Medium	Low-high
Absorption rate	Fast	Medium	Slow-fast

Ruiz & Montoto ADME Processes in Pharmaceutical Sciences 2018

Non-invasive routes

Enteral route

Oral

Non-invasive
Extended release (hours)
Large drug amounts

Bioavailbility can be low/variable

- Degradation of drugs in GI tract
- Low absorption due to epithelial barrier
- First pass metabolism

Prolonged release (days) challenging
Only if patient can swallow

Topical route

Transdermal

Non-invasive
Extended release (hours to days)
No first-pass metabolism
Also for patients who cannot swallow

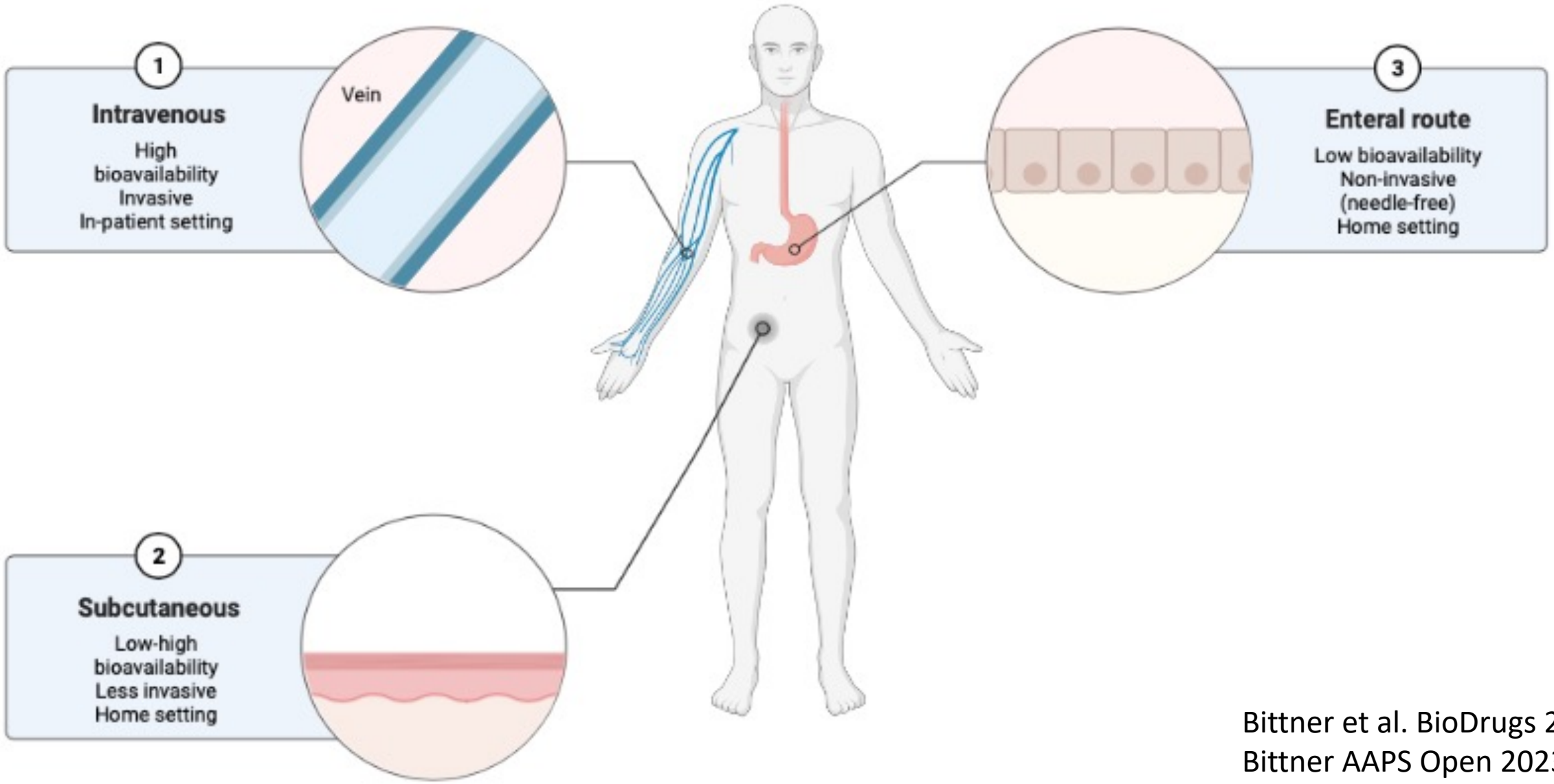
Bioavailbility can be low/variable

- Degradation of drugs in skin
- Low absorption due to epithelial barrier

Low/moderate drug loading capacity

Ruiz & Montoto ADME Processes in Pharmaceutical Sciences 2018

Antibody administration



Bittner et al. BioDrugs 2018
Bittner AAPS Open 2023
Pitiot et al. Antibodies 2022

CRS Skin & Mucosal Delivery Focus Group

- One of seven FG of the Controlled Release Society
- Over 250 members from academia, industry, and governmental organizations
- Aims
  - To be a leading forum to impact the forefront of delivery science specific to **skin and mucosal barriers**
  - To provide a dynamic platform, for like-minded professionals at all stages of their careers from academia, industry, and government, to
    - foster collaborations
    - enable networking opportunities and the exchange of ideas at the forefront of the field
    - increase member visibility and participation in the CRS and SMD FG
- Activities
  - Monthly webinars on skin and mucosal delivery with speakers from industry and academia
  - Member of the month
  - Scientific session at CRS annual meeting
  - Networking event at CRS annual meeting
- Currently setting up an industry subteam (Jill Steinbach-Rankins)

CRS Skin & Mucosal Delivery Focus Group

Focus Group TRANSDERMAL AND MUCOSAL DELIVERY

CRS Controlled Release Society

INTRODUCING OUR BOARD MEMBERS

Simon Matoori
(Université de Montréal)
Chair

Jill Steinbach-Rankins
(Boehringer Ingelheim)
Co-Chair

Justin Hanes
(Johns Hopkins University)
Board Advisor

Beate Bittner
(Roche)
Industry Representative

Thanh Duc Nguyen
(University of Connecticut)
Secretary

Davide Brambilla
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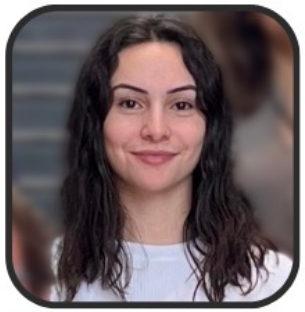
Treasurer

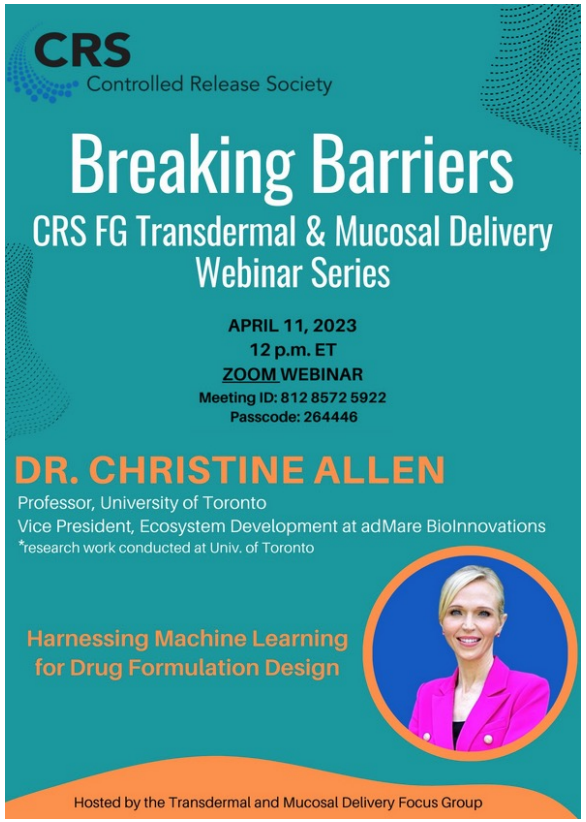
Helena Almeida
(i3S - Instituto de Investigação)
Student Representative



Natalie Guirguis
(Université de Montréal)
Social Media Team

Priyanshu Bharadwaj
(Université de Montréal)
Social Media Team

Breaking barriers webinar series



At this CRS Annual Meeting

Tomorrow at 9 PM!

Scientific session

Date: *Wednesday, July 26*
Session Time: 11:00 am - 1:00 pm
Session Title: *Skin and Mucosal Delivery (FG)*
Room Location: *Champagne 1 & 2*
Session Moderator: **Simon Matoori**
Discussion Moderator: **Jill Steinbach-Rankins**

Speakers: Justin Hanes (Johns Hopkins U), Christine Allen (U of Toronto), Stephen Buckley (Novo Nordisk), Xun Sun (Sichuan U)

Stay tuned

Become a member (free for CRS members) to receive email updates on all activities

Check out our Twitter page