

TRD/CPP & NDT



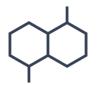
Novartis Global Healthcare

Meeting Patient Needs

Manuel Sanchez-Felix

CRS Annual Meeting: Montreal, Canada
14th July 2022

Content



Introduction



Access to Medicines



Pharma Industry Global Health Challenges



Publication



Summary

Introduction

- Novartis: Novel Drug Delivery Group
- Objectives:
 - Achieve a common understanding on “Global Health”
 - Provide an overview of Novartis Global Health Initiatives
 - Explain transition from “can we make it” to “does the patient want it and how can we supply the product to all”
 - Encourage you to think how you can help?



Access to medicine is where we believe we can have the greatest impact

2 billion

Patients do not get medicines they need¹

	Non-communicable disease (NCD)	Communicable disease (CD)
High-income countries	 <p>Health inequity leads to varying quality of care based on ethnicity, socio-economic factors</p> <p>CVD is the leading cause of death in US, highest risk among non-Hispanic Black populations and in areas with highest rates of poverty²</p>	<p>In US, 40% more black people have died from COVID-19 vs. white people³</p>
LMICs Dual burden of Non-NCDs (on the rise), CDs (unfinished agenda)	 <p>~300k infants are born annually with SCD, out of 10 are born in sub-Saharan Africa⁴</p> <p>>3/4 of CVD deaths take place in LMICs⁵</p>	<p>8 LMICs disproportionately affected by COVID-19</p> <p>274k children die annually of malaria⁶</p> <p>390m dengue virus infections / year⁷</p>

CVD – Cardiovascular disease LMICs – Low/middle-income countries SCD = Sickle cell disease

1 Access to Medicine Foundation; 2 <https://www.cdc.gov/healthequity/lcod/men/2017/nonhispanic-black/index.htm>; 3 COVID Tracking Project and the Boston University Center for Antiracist Research. <https://covidtracking.com/race>; 4 Global epidemiology of sickle haemoglobin in neonates: a contemporary geostatistical model-based map and population estimates. Piel FB, Patil AP, Howes RE, Nyangiri OA, Gething PW, Dewi M, Temperley WH, Williams TN, Weatherall DJ, Hay SI. Lancet. 2013 Jan 12; 381(9861):142-51.5; 5 <https://www.who.int/en/news-room/fact-sheets/detail/cardiovascular-diseases-cvds>; 6 <https://www.who.int/news-room/fact-sheets/detail/malaria>; 7 <https://www.who.int/news-room/fact-sheets/detail/dengue-and-severe-dengue>

Novartis Access Principles in practice to address unresolved global health challenges

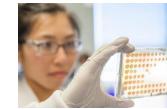


Malaria | 229m cases across 87 countries¹

Reached 1bn treatment courses of Coartem®

Ganaplacide / lumefantrine SDF met Ph2b primary study objective

Committed \$100m in R&D until 2023 in novel anti-malarials



Antimicrobial Resistance

Balanced, cross-sectorial approach



Sickle Cell Disease | 250m carry the gene²

~10k patients being treated with hydroxyurea
in Ghana & East Africa

Launched gene therapy R&D collaboration with BMGF



Chagas | Affects ~6m people worldwide³

1st of its kind clinical study in Latin America



Leprosy | 200k new cases annually⁴

Reached >7m patients

Renewed commitment with WHO: Extend Multi Drug therapy donation through end 2025



Avoidable Blindness

Strengthen and elevate eye health



COVID-19

Manufacturing agreements, investigating the DARPin platform

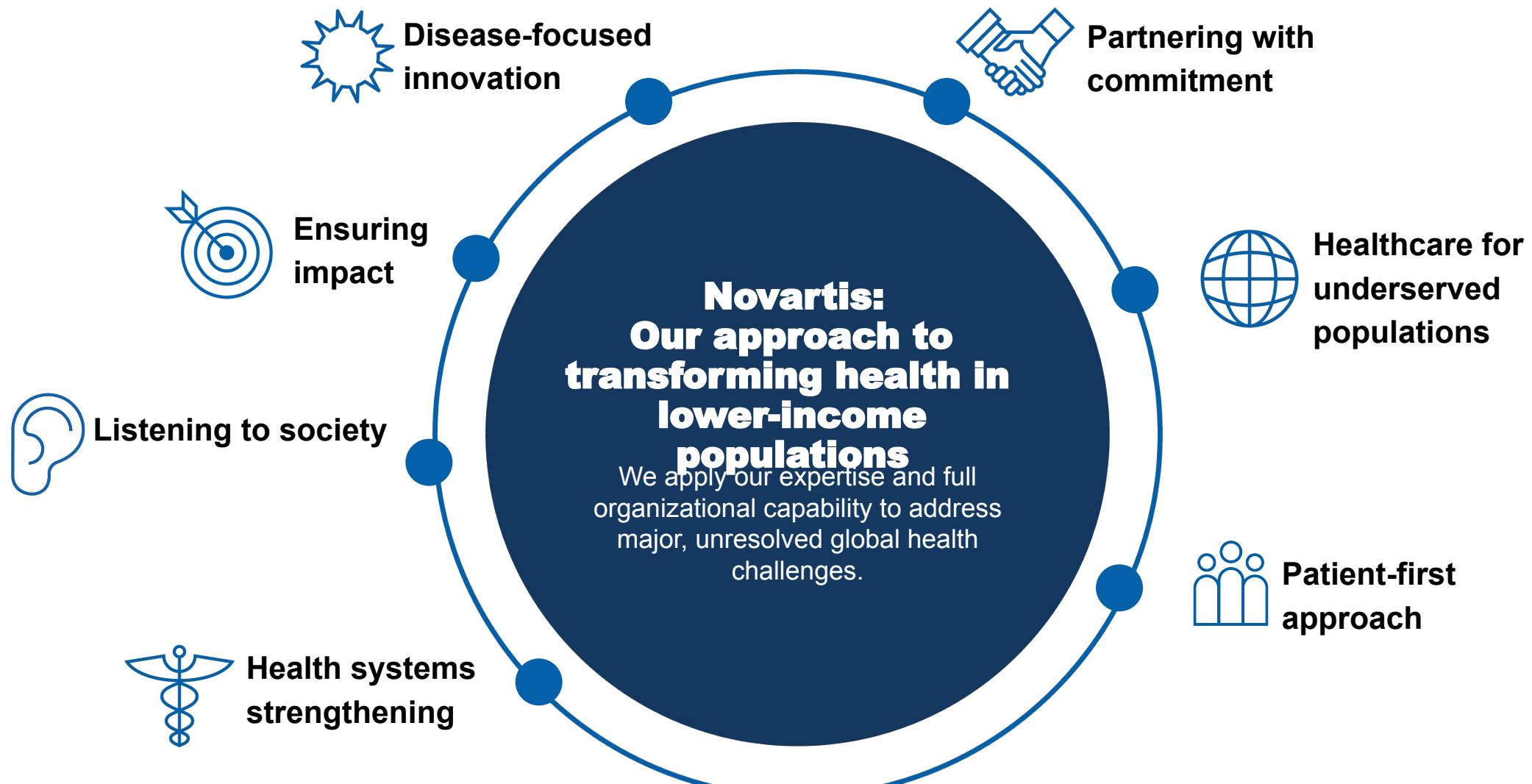
Our approach to access has evolved over two decades

2000	2001	2008	2014	2015	2017	2019	2020	2021
Sole donor to the WHO of multidrug therapy for leprosy	Antimalarial Coartem® (no-loss strategy) Crossed 1bn treatments in 2021	Healthy Family ¹	Local innovative brands in LMIC	Novartis Access ²	Novartis Access Principles	New strategy for Sub-Saharan Africa	Sustainability-linked bond	Co-create solutions to address root causes of health inequity in US
								

Donations > No-loss strategy > Sustainable business models, business-integrated solutions

1. Education / medicines to patients at the bottom of the income pyramid. 2. 15 on-off patent medicines for NCDs.

Transforming health in lower-income populations



Access to Medicines: Recent News

Novartis renews commitment to neglected tropical disease and malaria elimination, investing USD 250 million over five years to research and develop new treatments

Jun 23, 2022

- Novartis endorses the Kigali Declaration on neglected tropical diseases, pledging USD 250 million to advance R&D of new treatments against NTDs and malaria over five years
- Commitment includes USD 100 million to advance R&D for Chagas disease, leishmaniasis, dengue and cryptosporidiosis, and USD 150 million for next-generation antimalarials and a new formulation for babies under 5kg with malaria
- Around the world, 1.7 billion people suffer from NTDs¹, and there are 241 million cases of malaria²

Sandoz announces new global 'Act4Biosimilars' initiative, to improve patient access and increase adoption by at least 30% in 30+ countries by 2030

[Back to News Archive](#)

May 31, 2022

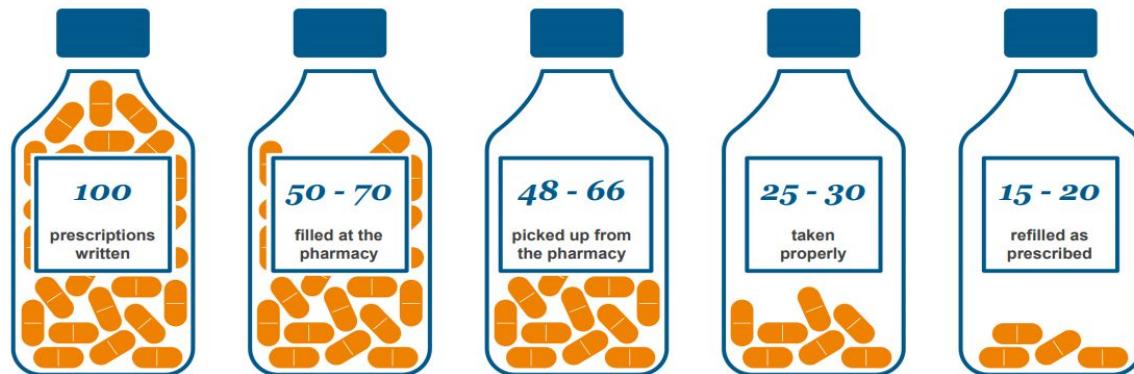
- Multidisciplinary Steering Committee established to drive action includes patient advocacy leaders, healthcare professionals, biosimilar experts and industry leaders
- Action Plan will provide roadmap and tools to improve approvability, accessibility, acceptability and affordability (4As) of biosimilars
- Sandoz launched initiative to support improved healthcare access, equity and sustainability

Pharma Industry Global Health Challenges

“Drugs don't work in patients who don't take them” former US Surgeon General, C. Everett Koop
How can we make Medicines that work for Patients by reducing burden?

Medication Adherence Represents A Significant Barrier To Healthcare

For Every 100 Prescriptions Written...



National Association of Chain Drug Stores, Pharmacies: Improving Health, Reducing Costs (March 2011)

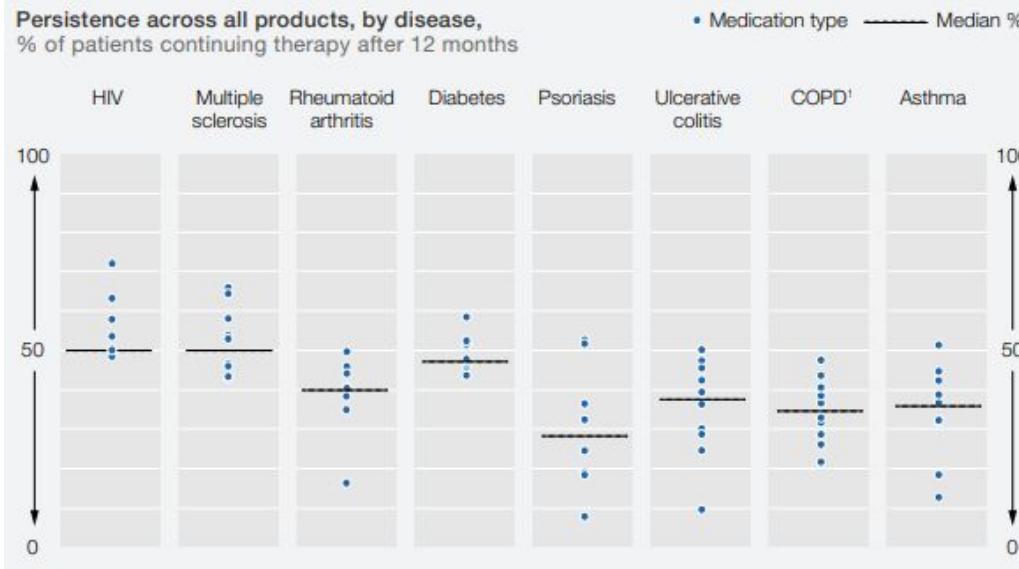
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MCKESSON

- We have a problem in high income countries with people taking their medicines
- The issue is greater in low & medium-income countries

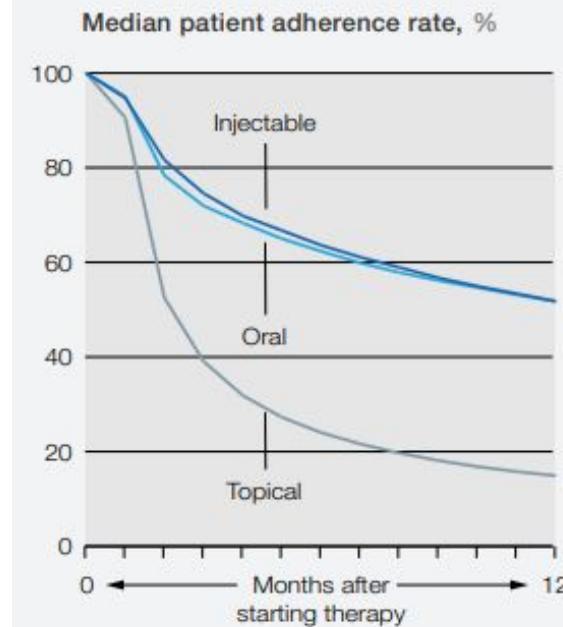
Pharma Industry Global Health Challenges

Low persistence rates were found across disease categories, with significant variation by medication within each category.

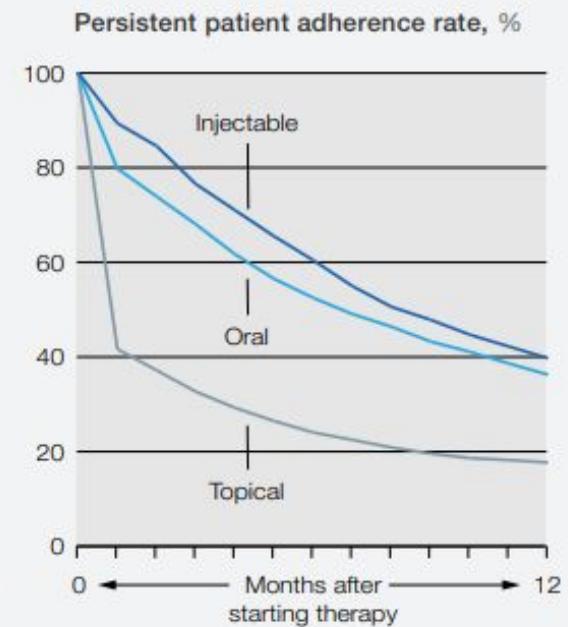


McKinsey&Company

Delivery methods show wide variations in **psoriasis**-treatment adherence.



McKinsey&Company



- HIV has some of the highest persistence rates because the patients, healthcare systems and pharma industry recognize the issue and work together
- Still opportunities to improve

Pharma Industry Global Health Challenges

1. Dropout rates and poor adherence are different but linked to patient burden
2. Chronic diseases and poor adherence are linked
3. **Low & middle-income countries need medication for all diseases**

Medication Adherence in Common Chronic Diseases*	
Disease State	Mean (Range [%]) Medication Adherence Rate
Cancer	80 (35-97)
Cardiovascular diseases (all)	71 (39-93)
Hypertension	73 (39-93)
Psychiatric illnesses	78 (75-83)
Epilepsy	70 (46-88)
Glaucoma	78 (76-80)
Diabetes mellitus	73 (66-85)
Asthma	55 (37-92)
Chronic obstructive pulmonary disease	51 (50-52)

J Manag Care Pharm. 2006; 12(6).
Clin. Ther. 2001 Aug; 23(8):1296-310.

Establishing Patient Needs?

Carrier 2:08 PM Page 32 out of 78 100% Back Next

Can you spot the differences in pictures 1, 2 and 3?

1 Intramuscular (IM) 2 Subcutaneous (SC) 3 Implant (IMPL)

Comment here

Carrier 2:09 PM Page 43 out of 78 100% Back Next

SECTION 3
Please PICK 1 OPTION on the screen that you LIKE the BEST. INTERVIEWER-NAME can help explain the DIFFERENCES and the SIMILARITIES.

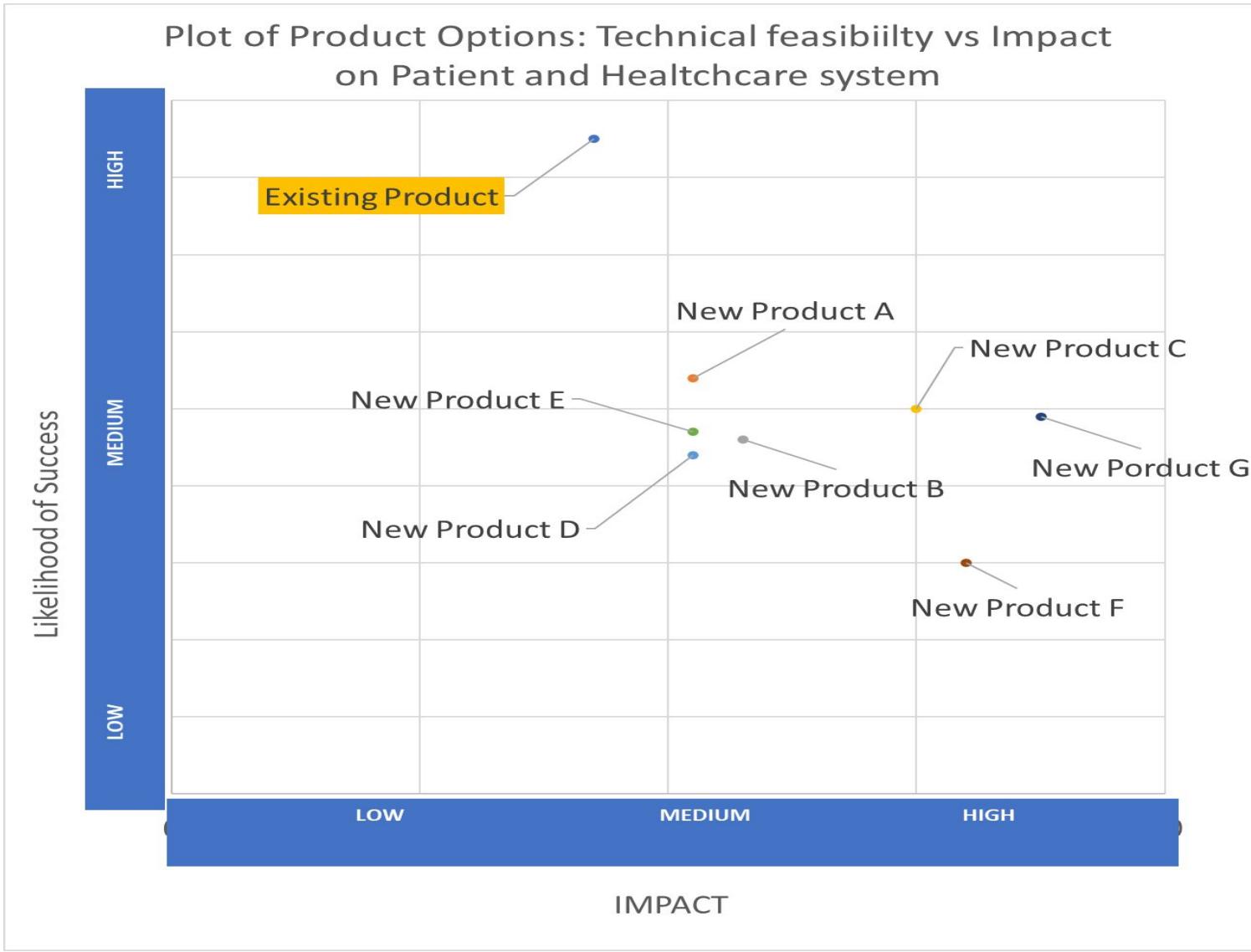
Intramuscular (IM) single, 2.0 mL 1 month

Implant (IMPL) small, double 3 months

less than 5 minutes less than 15 minutes

Comment here

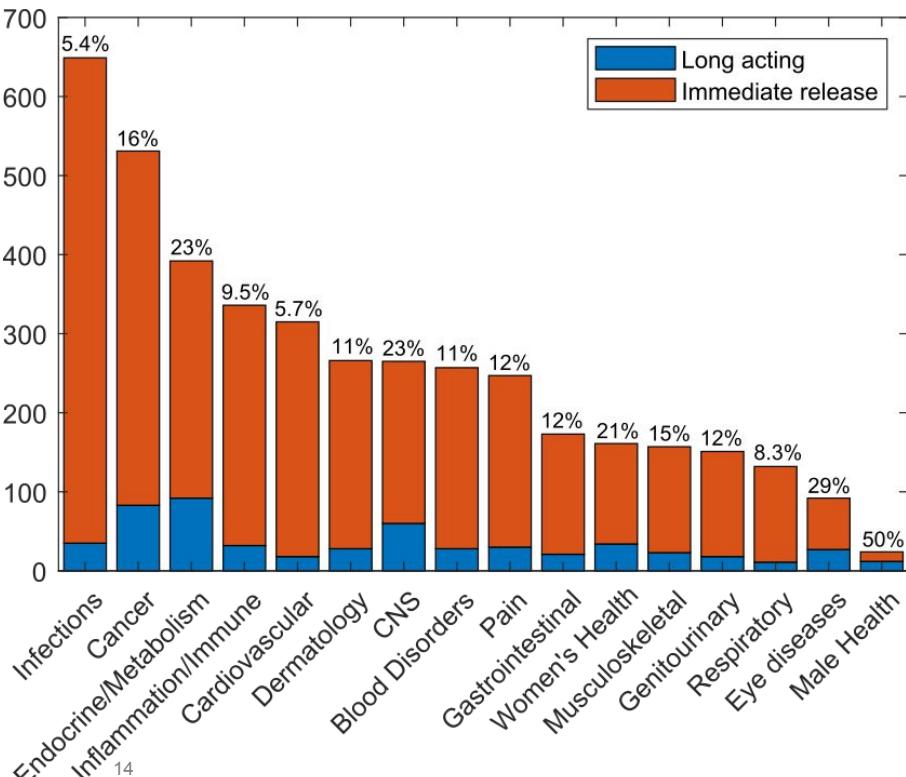
Evaluating Product Ideas



Smart design of patient centric long-acting products: from preclinical to marketed pipeline trends and opportunities

Celine Bassand*, Alessia Villois*, Lucas Gianola, Grit Laue, Farshad Ramazani, Bernd Riebesehl, Manuel Sanchez-Felix, Kurt Sedo, Thomas Ullrich, Marieta Duvnjak Romic

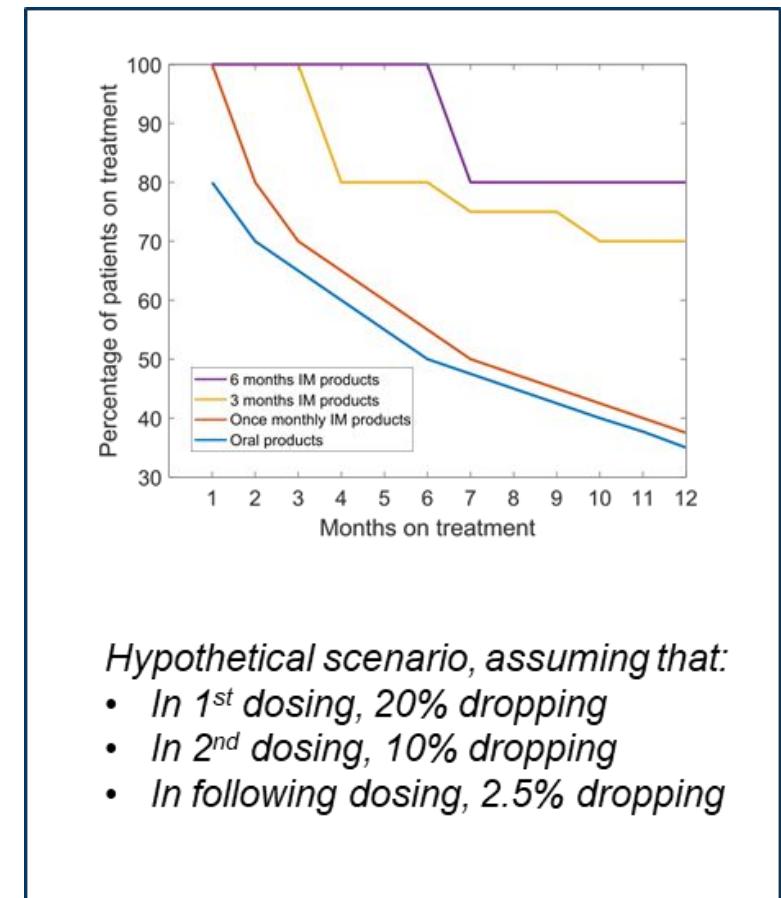
*These authors contributed equally to this work, co-first authorship



Depending on the disease area, long-acting injectables account for 5%-50% of all approved products

- Data from PharmaCircle
- No distinction of DS type
- US, EU and Japan markets
- Duplicates not removed
- Orals not included

Submitted: Includes parenteral and oral LAI



Summary

- Global Health aim is to provide access to treatments for all patients across the world
- Patient focused product design is essential to provide access to the right treatment to patients, irrespective of geography or income
- Pharma companies have different disease focus areas and strategies for Global Health
- Highly collaborative environment and partners are required: Gates foundation, WHO, Welcome Trust, pharma, etc.
- Extended release can reduce the burden for patients and healthcare systems
- Oral LAI technologies are being developed
- **Question: How can you help us meet Global Health needs?**

Acknowledgements

- Colleagues at Novartis
 - Margaret Maloney, Jonathan Spector, Sonita Chada-Grathwol
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- Dr Jonathan Carapetis & Laurens Manning





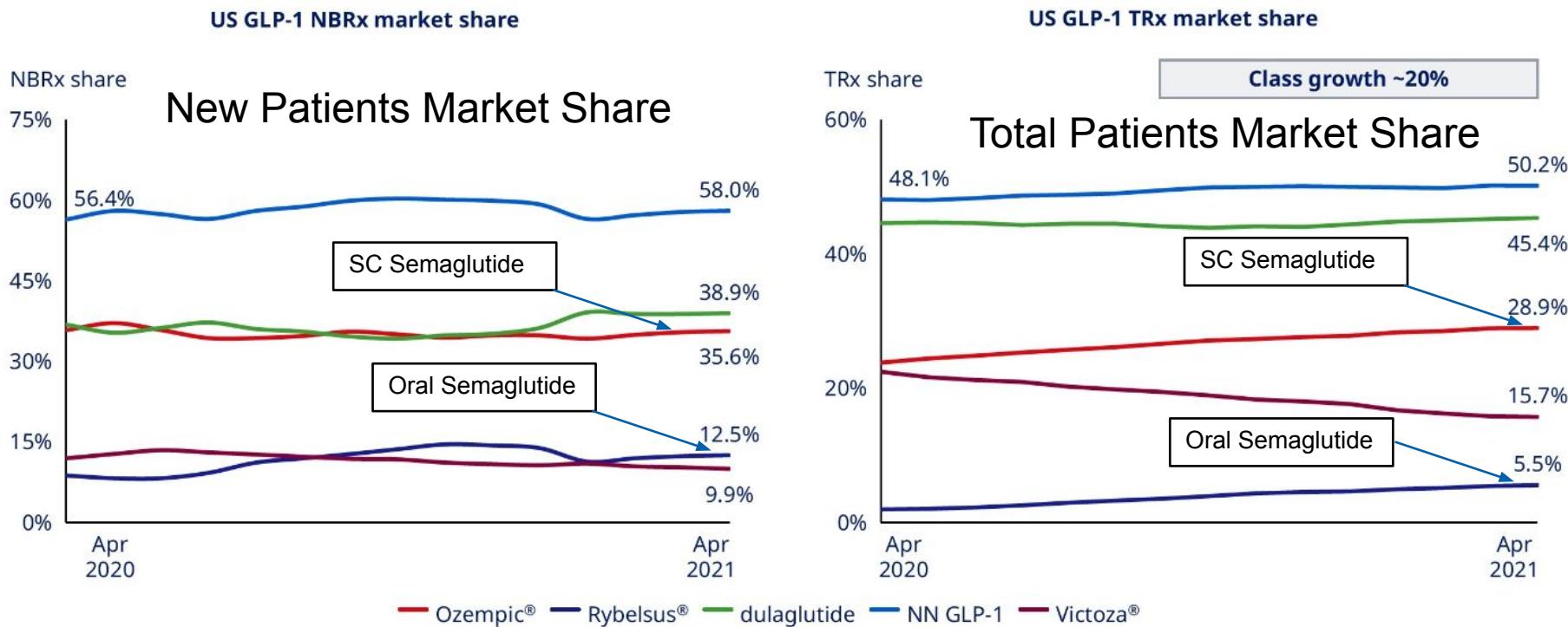
Thank you

Trends in Route of Administration Drug Delivery

7 Investor presentation First three months of 2021

Novo Nordisk®

In the last 12 months, Novo Nordisk increased market share in the fast-growing US GLP-1 segment



- Subcutaneous once weekly GLP1 are ~88% of the market
- Oral meets ~12% of population who have needle phobia