Are Drug Safety Measures Harmonized? A Real-World Data From Three Regulatory Authorities

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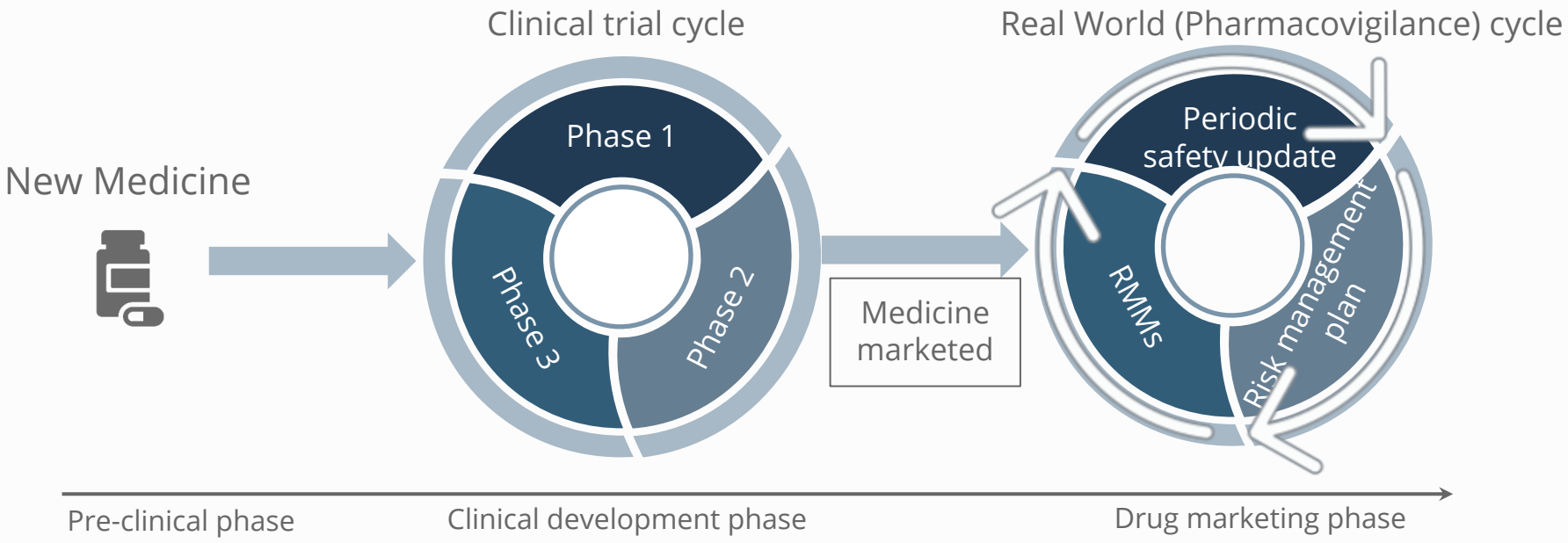
Introduction and Literature Review

The Drug Cycle



What are RMMs?

- Risk minimization measures (RMMs) are interventions intended to decrease or prevent the occurrence of adverse events associated with medications
- Regulatory authorities, including SFDA, FDA, and EMA lists risk minimization measures in their websites for specific medications

Saudi Food and Drug Authority (SFDA)
Food and Drug Administration (FDA)
European Medicines Agency (EMA)

Published Literature on Differences Between Regulators

FDA vs. EMA	A study conducted in **2012** showed differences in RMMs, including: • Differences in type of medications with risk measures • Differences in documents/information across some medications Study investigators suggested to update this comparison but no such update has been done
SFDA vs FDA and EMA	• No study evaluated the differences between the published RMMs

Lis Y. et al. Value in Health. 2012;15(8):1108-1118. doi:10.1016/j.jval.2012.06.019

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Significance of The Study

- It is essential to have a consistent risk and benefit minimization measures across regulatory authorities
- Differences in risk measures can impact medication use especially post-marketing
- Unified RMMs data will facilitate the exchange of information between the regulators

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Study Aims and Objectives

Overall Study Aim

To compare the differences in RMMs between the SFDA, FDA, and EMA, in order to investigate whether there is a variability in measures done to optimize the risk and benefit of chemical entities and biologics

Study Objectives

1. To describe the medication lists with RMMs across different regulatory authorities
2. To compare the details of RMMs across regulatory authorities

Risk Minimization Measures (RMMs)
Saudi Food and Drug Authority (SFDA)
Food and Drug Administration (FDA)
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03

Study Methods

Study Design, and Source of Data

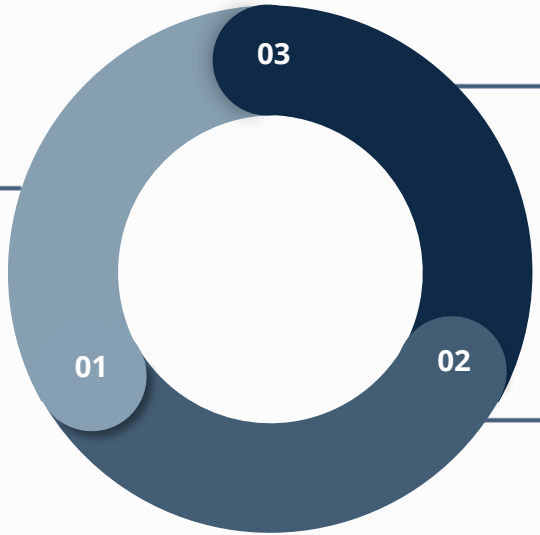
- Observational study
- Electronic search was done to retrieve publicly available information and documents of RMMs from the SFDA, FDA, and EMA websites
- All data are freely available online in regulators websites.
    - These medication data, do not include any patient information, therefore no IRB approval was needed for this study

Risk Minimization Measures List | Saudi Food and Drug Authority. Sfda.gov.sa. https://www.sfda.gov.sa/en/RMM?keys=&tags=49&field_risk_minimization_type=All
Risk Evaluation and Mitigation Strategies (REMS). U.S. Food and Drug Administration. https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems
Risk management plans - European Medicines Agency. European Medicines Agency. https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/pharmacovigilance/risk-management/risk-management-plans

Data Collection Process

Collect medication lists with RMMs data

Regulators websites were accessed to determine list of medications with RMMs



Content comparison

All risks and types of RMMs were compared

RMMs lists extraction

Medications with the same trade name were matched, then details of medication risks and RMMs content were extracted from each medication with RMMs in each regulatory authority

Risk Minimization Measures (RMMs)
Saudi Food and Drug Authority (SFDA)
Food and Drug Administration (FDA)
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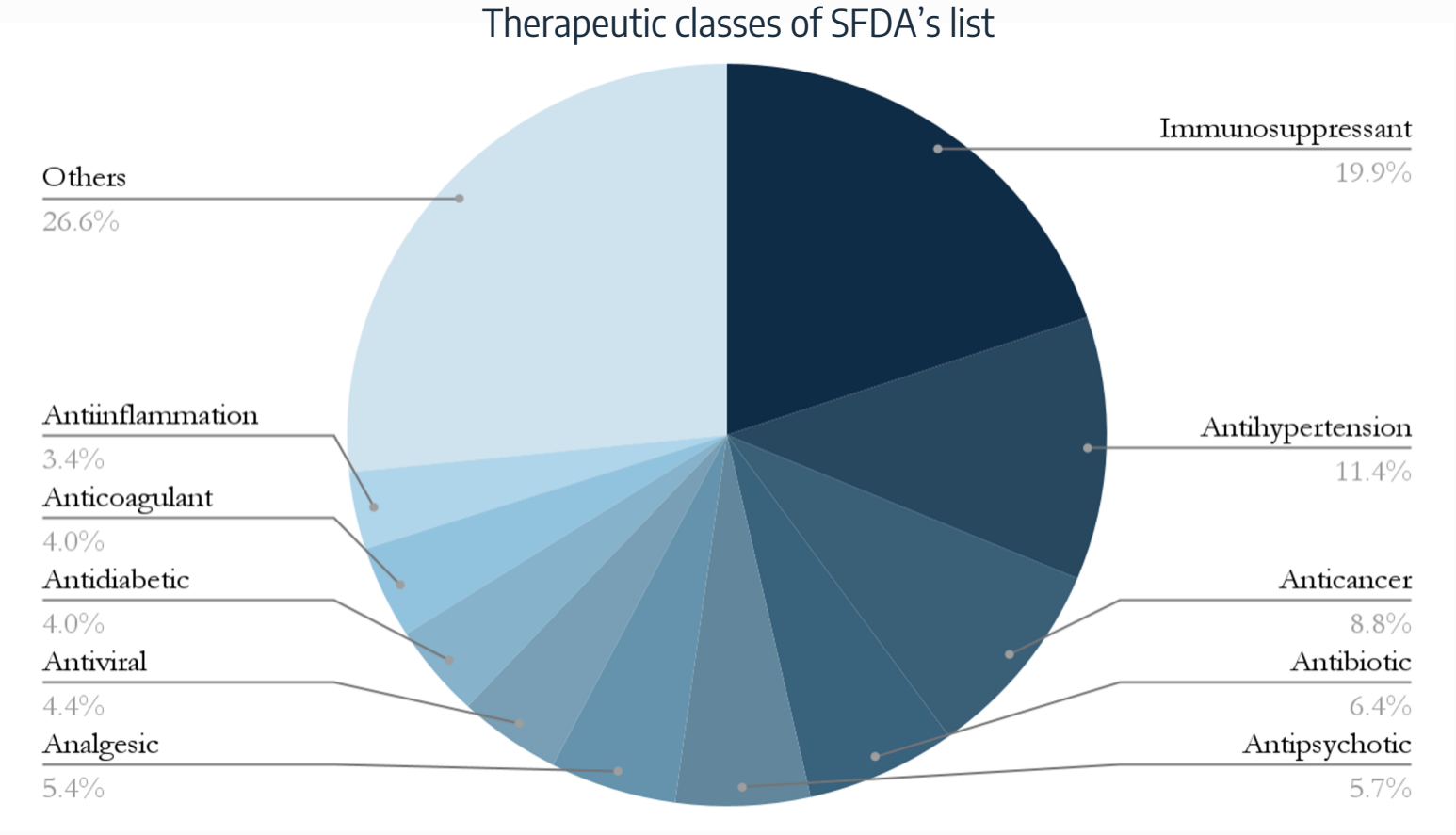
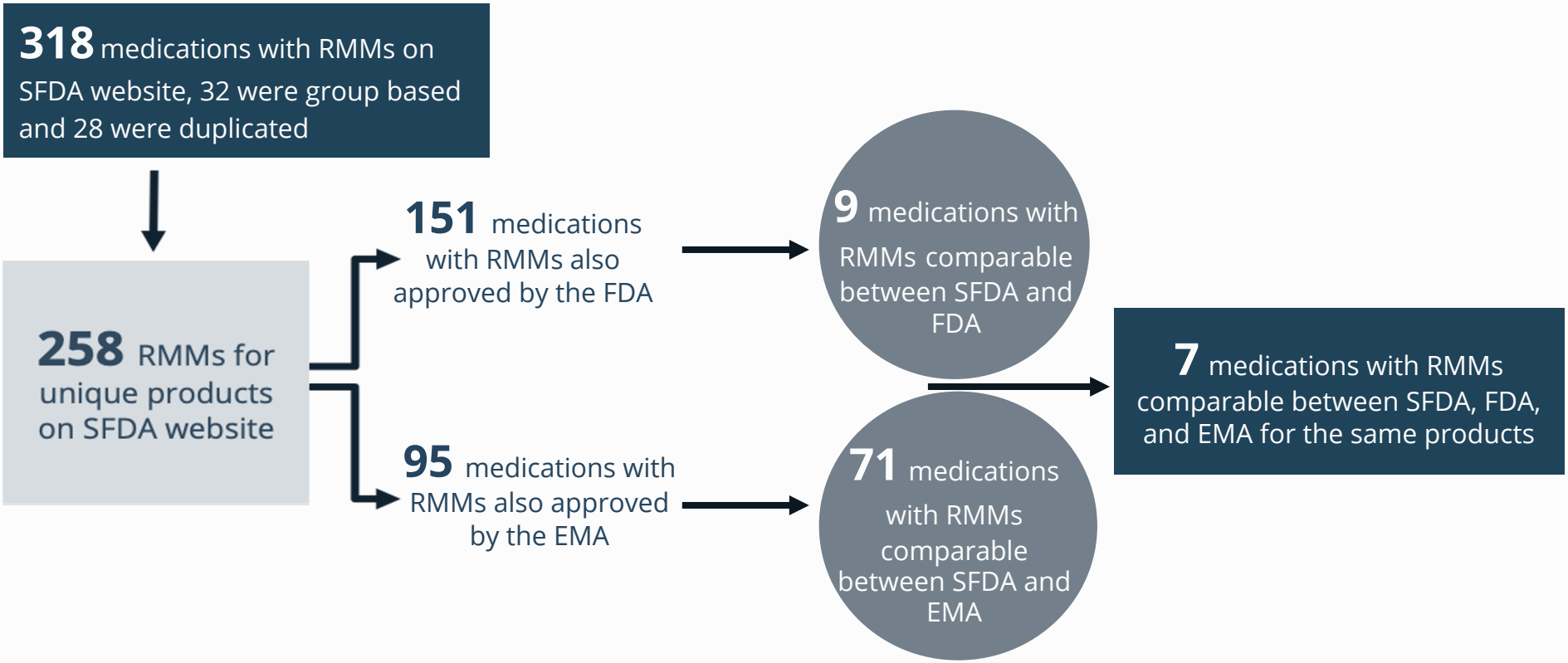
Study Results

Medications with RMMs in the SFDA's (n=318)



Medications with RMMs in Each Regulatory Authority



The 7 Matched Medications with RMMs Between Regulators

Trade name (Scientific name)	Manufacturer name	RMM comparison
Blincyto® (Blinatumomab)	Amgen	Similar
Kymriah® (Tisagenlecleucel)	Novartis	Similar
Lemtrada® (Alemtuzumab)	Sanofi	Similar
Tracleer® (Bosentan)	Janssen-Cilag	Different
Revlimid® (Lenalidomide)	Bristol-Myers Squibb Pharma	Similar
Prolia® (Denosumab)	Amgen	Different
Tysabri® (Natalizumab)	Biogen	Different

Selected Examples for RMMs Content Comparison

Drug name	Risk	SFDA	FDA
Caprelsa® (vandetanib)	QT prolongation, Torsades de pointes, and sudden death	No RMM	Patient Brochure, Pharmacy Enrollment Form, Prescriber Enrollment Form
Remsima® (Infliximab)	Risk of Serious infections and HBV reactivation	HCP checklist, HCP guide, Patient card	No RMM

Health care provider (HCP)
Hepatitis B virus (HBV)

Selected Examples for RMMs Content Comparison

Drug name	Risk	SFDA	EMA
Ozurdex® (dexamethasone)	Increased intraocular pressure, Glaucoma, Endophthalmitis, and Ocular hypertension	No RMM	Patient guide
Revolade® (Eltrombopag)	Hepatotoxicity, Thrombotic/thromboembolic complications, Bone marrow reticulin formation and fibrosis, Haematological malignancies, and Post therapy thrombocytopenia	Patient support booklet, HCP safety guide	No RMM

Health care provider (HCP)

Conclusion

- This study shows substantial differences among the regulatory authorities regarding RMMs
- Harmony in published risk measures can have a significant impact on medication safety

Thanks

Feel free to ask

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