IQVIA
CONSUMER HEALTH

# New Paths to Applying RWE to OTC Medicines

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# Speakers

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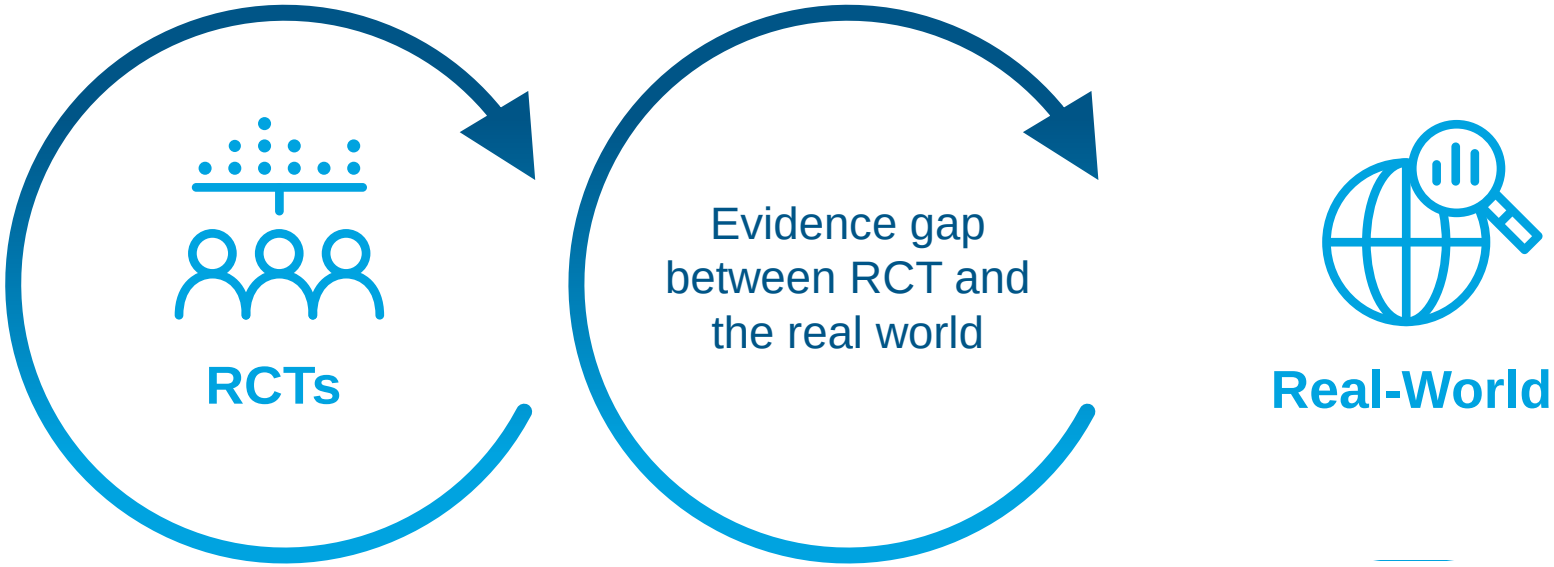
# RWE and OTC today

# In the past, evidence to support decision making during the life cycle of OTC drugs was primarily generated through «classic» clinical research methods

## Randomized-controlled clinical trials as «gold standard» come with certain limitations



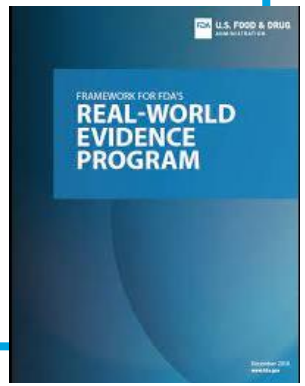

**New types of evidence collected in a Real-World situation can be applied to complement findings from RCTs**

# In Pharma, Real-World Data (RWD) and Real-World Evidence (RWE) are playing an increasing role in health care decisions

According to US FDA's definition, RWE is **the clinical evidence regarding the usage and potential benefits, or risks of a medical product derived from the analysis of RWD**.

... As part of its RWE Program, FDA committed to understanding the full potential of RWD and RWE in regulatory decision-making.

4 Aug 2021




https://www.fda.gov/drugs/news-events-human-drugs/fda-approval-demonstrates-role-real-world-evidence-regulatory-decision-making-drug-effectiveness

RWE is the **information derived from analysis of RWD**.

In EMA, RWE is widely used in restricting and extending indications, making labeling changes, accessing benefit-risk, and the withdrawal of marketing authorization.

31 May 2021

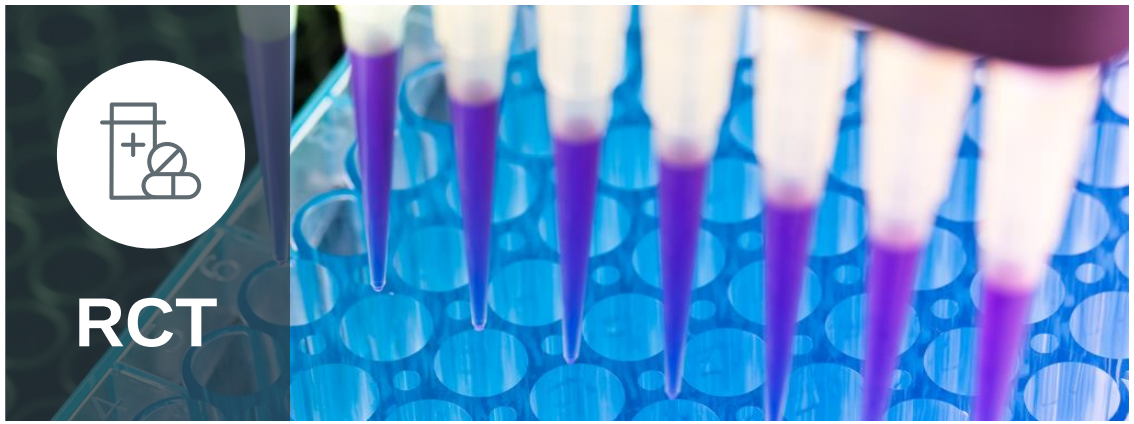
Front Med (Lausanne). 2021; 8: 669509.

**EMA study reveals need for RWE framework, submission structure (2021)**

**What does this mean for Consumer Health and OTC?**

# How can real-world evidence aid decision making during the life cycle of non-prescription medicines?

# How can RWE be applied to decision making for medicines?




- High internal validity
- Remain necessary to demonstrate efficacy and safety for new drug approvals


- Higher external validity
- Can complement evidence derived from RCTs
- Understanding of outcomes outside of a controlled setting.
- Can help to fill important data gaps when RCTs are not feasible or appropriate.

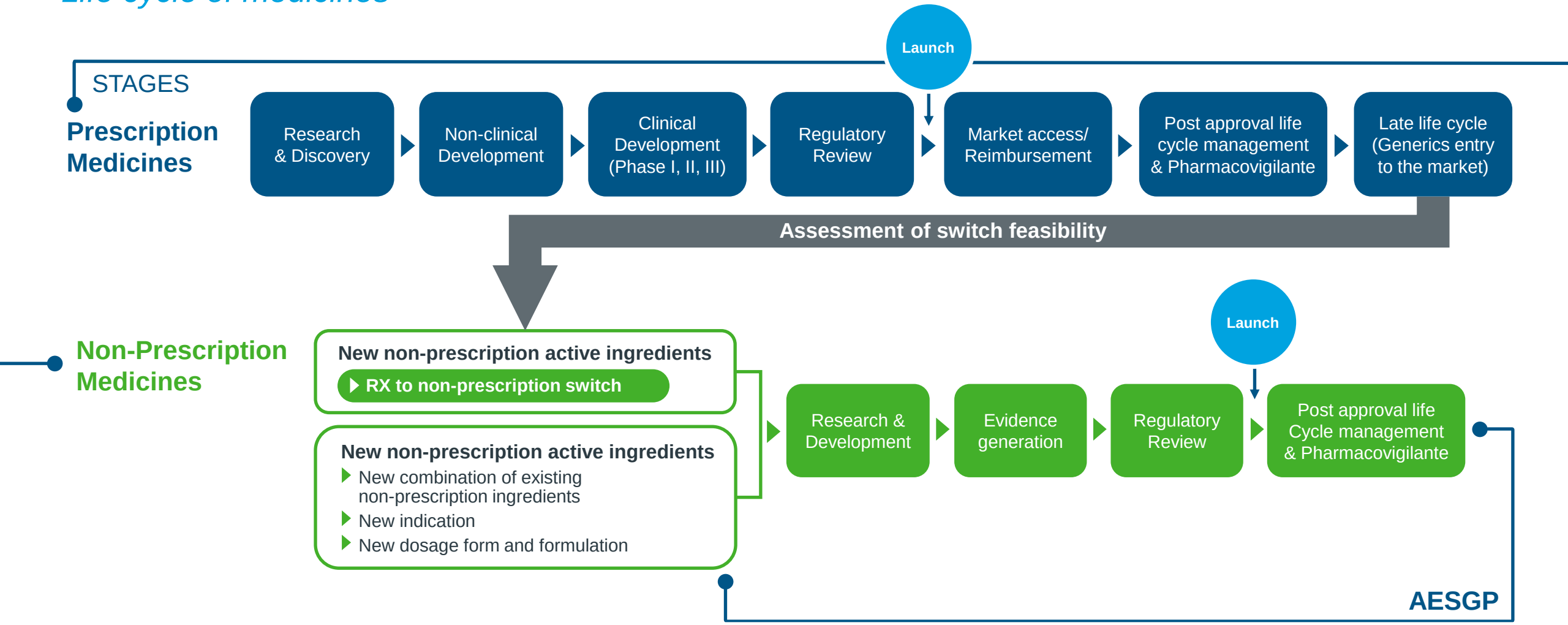
**Current limitations of RWD:**

- incomplete and non-standardised
- comparisons are complicated by confounding factors

Compared to Rx, there has been little focus on **the potential role of RWE for OTC medicines.**
**0.22%** of overall RWE publications included keywords relevant to OTC!

# The non-prescription medicine life cycle

*Life cycle of medicines*



# Real-world evidence – where is the data sourced?

01

## Non-prescription Medicines

- Purchased **without** doctor's prescription
- EHR* and insurance claims data are **not** routinely available
- The wealth of information on the real-world use of OTC medicines is largely uncaptured

02

## Prescription Medicines

- Purchased with doctor's prescription
- **EHR*** and insurance claims data is routinely available

| | Prescription-only medicines | Non-prescription medicines |
|---|---|---|
| Spontaneous adverse event reporting | ✓ | ✓ |
| Real-world studies | ✓ | ✓ |
| Population health surveys | ✓ | ✓ |
| Social media | ✓ | ✓ |
| Patient/consumer surveys | ✓ | ✓ |
| Health apps | ✓ | ✓ |
| Electronic health records | ✓ | |
| Claims databases | ✓ | |
| Prescribing data | ✓ | |
| Patient and drug registries | ✓ | |
| Consumer grade medical devices | ✓ | |
| Consumer wearables | | ✓ |

**Real-world data source comparison**

# Defining real-world data to enable use with OTC medicines

*RWD is a broad term which lacks a single internationally agreed definition*

| | **EMA** (Cave at al) | **FDA** (FDA RWE Framework) |
|---|---|---|
| **RWD** | **Routinely collected** data relating to a patient's health status or delivery of health care from a variety of sources other than traditional clinical trials | Data relating to patient health status and/or the delivery of health care **routinely collected** from a variety of sources |
| **RWE** | The information derived from analysis of RWD | Clinical evidence about the usage and potential benefits or risks of a medical product derived from analysis of RWD |

## Different approach needed for OTC

RWD should be defined widely by regulators

**"Data used for decision making that are not collected in conventional randomised controlled trials".**

Includes both: routinely collected data + data from RWTs

References
Cave, A., Kurz, X., Arlett, P. (2019). Real-World Data for Regulatory Decision Making: Challenges and Possible Solutions for Europe. Clin. Pharmacol. Ther. 106(1), 36–39. https://doi.org/10.1002/cpt.1426
Framework for FDA's Real-World Evidence Program. U.S. Food and Drug Administration (FDA). <www.fda.gov / https://www.dropbox.com/home/AESGP_RWD_RWE_WG/References/Health_Authorities?preview=FDA_Framework_RWE_2018.pdf>
Garrison LP, Neumann PJ, Erickson DM et al. Using real-world data for coverage and payment decisions: The ISPOR real-world data task force report. Value in Health. 2007; 10(5):326-335
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# Panel Discussion

# Q – Data Gaps

1. How can we foster routinely collected data for OTC as well as encourage the consideration of observational data around non-prescription medicines?
2. Is patient generated health data a real opportunity for OTC RWE?

# Q- Where might RWE aid decision making when it comes to OTC medicines?


# Aiding decision making – RWE/OTC examples

**Rx-to-OTC Switch**
Orlistat | Flurbiprofen

**Real Life Effectiveness**
Nicotine Replacement Therapy

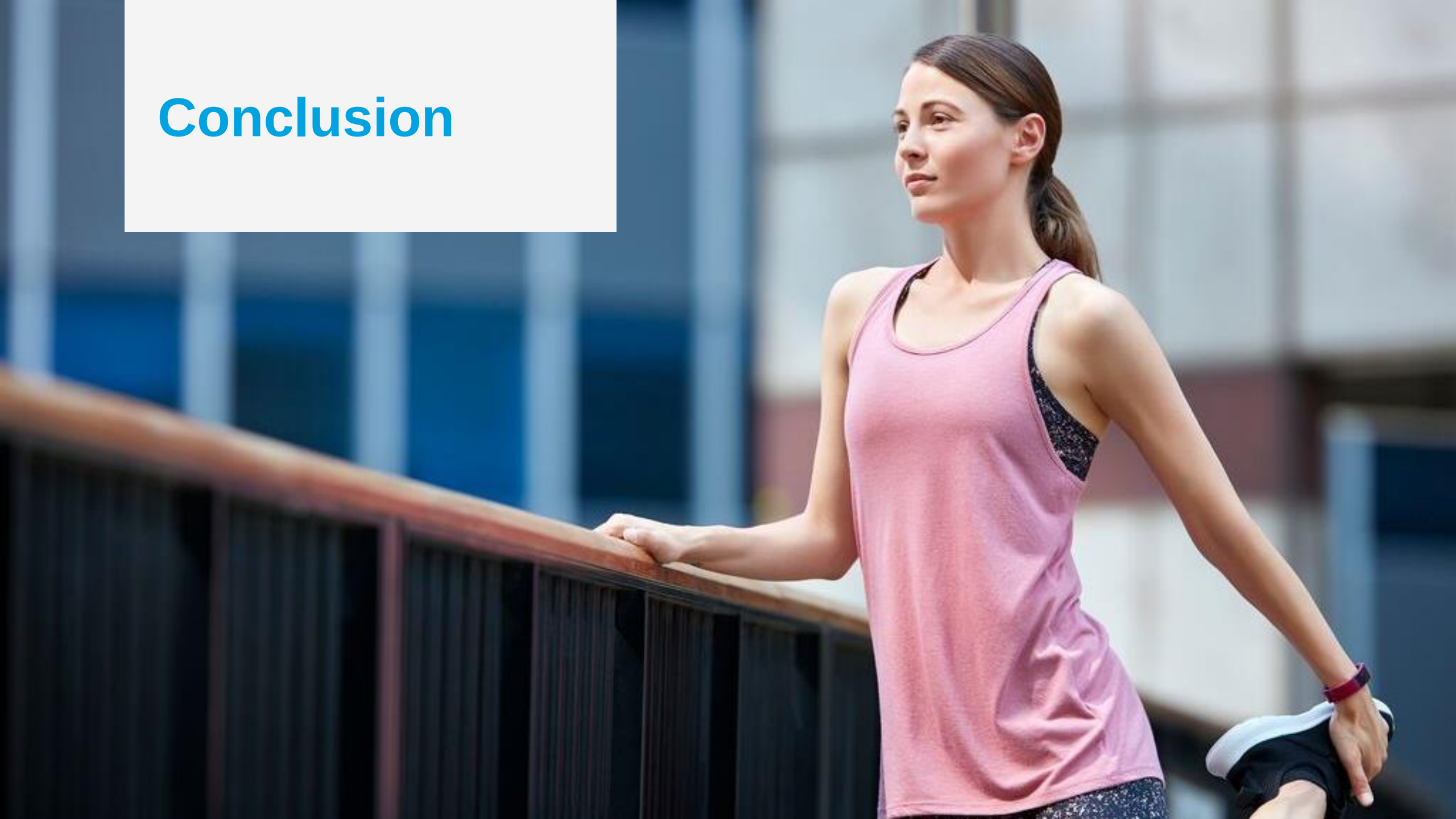
**Post-Marketing Safety**
Ibuprofen

# Q- What are the biggest hurdles at the moment for utilizing RWE in the OTC space?

**Q- What is the one thing that needs to happen next to ensure the power of RWE can be harnessed to help drive the future of OTC medicines?**

# Q&A

# Conclusion



# What is needed to make RWE and digital research successful now?

*Start to engage and create high-quality outcomes to convince regulators*


## Advantages

- Opportunities for new claims and indications
- New type of insights & evidence – consumer focused and relevant
- Improved efficiencies applying virtual / digital research methodologies

## Success

- Be open to innovate how to approach evidence generation despite uncertainties
- Collaborate with regulators and RWE experts
- Consumers first – but be careful to ensure strong scientific methodologies and technologies

> The time of real-world evidence (RWE) and big data is now. With the benefits of RWE manifold, there were lots of opportunities for the self-care industry.

**Dr. Peter Arlett, Head of Data Analytics and Methods Taskforce at EMA**
**AESGP Annual Meeting – May 2021**

# Your IQVIA Consumer Health contact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Or visit iqviaconsumerhealth.com for more information

# Thank You