Can social media data be used to support evidence generation?

28 November 2024

Session 3 of the HMA/EMA Big Data Stakeholder Forum: Evidence generation to advance regualtory excellence, preparing for tomorrow

Presented by **Eleonora Agricola** (HMA-EMA Big Data Steering Group member, as EU Innovation Network representative; AIFA)

The History of Italian Small Squares

Piazzas in Italy have ancient roots that date back to Roman times. Originally, they were open spaces intended for trade, public meetings and religious celebrations. Over the centuries, these squares have transformed into real centers of social aggregation. In small towns and villages, piazzas have always been the focal point of community life, a place where inhabitants could meet, exchange news and opinions.

Daily Life in Small Piazzas is a succession of activities and moments that reflect the rhythm of local life. Piazzas are also places where political, religious and social demonstrations are held, reflecting the importance of these spaces in public life.

Social Media as a contemporary worldwide *Piazza* (Square)?

Worldwidely used.

Users' engagement.

Posts on opinions, experiences, questions.

Millions of users and posts rapidly accumulating & large datasets:

- Data generated voluntarily during daily life.
- Data specific to an individual or non-specific.
- Demographic and geographic data.
- Data access limited by data protection regulations, the platform's policy, and the type of data.

Social Media and health-related data

European Medicine Regulatory Network

Healthcare Professionals

Clinical outcomes perspective

Clinical knowledge

Education vs misinformation

Patients

Information and advice seeking

Sentiments and attitudes

Quality of life, use of medicines (PED)

Patient recruitment
Data collection
Study design
Evaluation RMMs

Proactive engagement in **investigating new data sources**.

Analysis in the **context** of **RWD** and **RWE**.

Potential **utility** for regulatory decision-making?

What are **impact, reliability, relevance, accuracy**?

What are **challenges** and **opportunities**?

5

Social Media for regulatory decision-making? HMA
Heads of Medicines Agencies

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 September 2024
EMA/348808/2024

Social Media Data for Real World Evidence in Regulatory Decision Making

An expert review report for the HMA/EMA Big Data Steering Group - 2024

A reference/starting point
Reflections on the current data/technological landscape

Use Cases for regulatory decision-making

Use case objective

1. Support the planning of applicant studies	2. Understand clinical context	3. Investigate associations and impact	4. Monitor, prepare for, and address public health challenges
Design and Feasibility	Disease Epidemiology Clinical Management Drug Utilisation	Effectiveness & safety studies Impact of Regulatory Actions	Supply & Availability of Medicines Public Health Emergency Detection Misinformation & Stakeholder Communication

Design and Feasibility

Recruitment & Screening
- Simple and early assessment of participant eligibility via social media (though significant ethical and methodological considerations)

Data collection
- Dissemination of surveys and questionnaires for data collection

Patient prevalence
- Insights on geographic patient and disease prevalence from analysing location information on social media posts

Study population
- Access to varied and some often-underrepresented populations, e.g. pregnant individuals or patients with co-morbidities

Patient led research
- Source of information and platform for patient advocacy, research, and scientific data sharing

Use Cases 2. Understand Clinical Context

Disease Epidemiology

Disease spread and epidemiological course

- Tracking of disease mentions in social media discussions, using AI and ML methods

Symptom Clustering

- Extraction of patient descriptions of symptoms and disease presentation

Clinical Management

Barriers to care

- Descriptions of different obstacles restricting patient access to available care.

Description of clinical care

- Mining patient discussions on care experiences to supplement the understanding of clinical management.

Drug Utilisation

Off Label use

- Inform on how medicines are being used beyond their approved indication via online discussions.

Alternate drug use patterns

- Gathering different drug schedules and doses that patients describe online

Reasons for discontinuation

- Collecting patients' reasons for not using certain products.

Unmet needs
- Inform on areas of unmet medical needs thanks to discussions around access and patients drug use.

9

Effectiveness & Safety

ADR Detection

- Cost-effective and early detection of ADRs
- Particularly useful for finding novel and mild/less severe ADRs

Effectiveness

- Gathering insights on effectiveness from patient-focused platforms that employ standardised questionnaires
- Insights into drug effectiveness from online drug related discussions

Impact of Regulatory Actions

Patient and HCP awareness of RMMs

- Analysis of awareness of risk minimisation measures for different user groups

Measure Impact over time

- Investigation of changes in awareness via analysis of metadata content (time and location data)

Supply & Availability of Medicines

- Monitoring SM data for earlier insights into potential shortages in cases with high media attention

Public Health Emergency Response

- Mining social media platforms for mentions of emerging threats
- Leveraging these findings for emergency response strategy

Misinformation & Stakeholder Communication

- Gathering information about misinformation as a public health threat
- Findings can then be used to guide stakeholder communication.

Challenges & Opportunities

Operational **Technical** **Methodological**

Artifical Intelligence

Access:
- unstable
- restricted

Data Protection:
- sensitive data
- re-identification

Reliability & Quality:
- Duplicated/irrelevant posts
- Language (misspellings and colloquialism)
- Video/image/audio analysis

Regulatory Support Tools

Limited regulatory experience and confidence

Patient focused platforms

Ethics:
- (Un)availability of patient consent
- expectations of privacy

Incompleteness:
- No past treatment and medical history
- Less discussed medicinal products

Integration

Population Representativeness

Points for consideration for future actions

Operational

1. Expedite access to social media data

- Facilitate access through:
  o Partnerships with SM companies
  o Launch network work program on social media data

2. Increase discoverability of RWD sources and studies using social media data

- Update RWD Catalogue with social media specific tags and filters

3. Engage and collaborate with all actors in the healthcare sector and leverage ongoing initiatives on PED

- Promote early interaction (SA, ITF and SME meetings) with regulators
- Organise a multistakeholder workshop to discuss the report's outputs and agree EMRN vision
- Leverage social media data in PED work and explore use of such data in regulatory decision making, particularly where scientific literature is still emerging (e.g. Long-COVID)

4. Draft a guiding principle on the ethical considerations for the use of patient data from social media

- Explore ethical EMRN use of social media data
- Draft guiding principles for proper use of social media data
- Prioritise analysis of social media data already available on public discussions

Points for consideration for future actions

Technical

5. Launch proof-of-concept studies on use of SM data for regulatory decision making

- Possible EMA scientific committees studies:
  - COMP – understanding unmet needs and burden of current treatments
  - PDCO – gathering paediatric PED on medicines
  - PRAC – understanding drug misuse & abuse
- Possible EMRN studies:
  - Explore use of social media for supporting Network response to public health threats
  - Explore use of social media data for Shortage monitoring

Methodological

6. Support initiatives for further development and validation of new methods to analyse SM data

- Review social media use in MAAs, SAs, and ITFs and share lessons and plans for future guidance
- Support network initiatives to investigate and develop new methods for analysing social media data
- Regulatory Science Research Needs RP6: *Develop methodologies and perform an analysis of the impact of social media on key medicines' availability*

Social Media as RWD in the EU regulatory network

Social media could have **different utility and impact** for regulatory decision-making

Timely monitoring tool and near real-time stakeholders' **listening**

Potential value to **communicate** directly with patients and a possible role to combat **misinformation**

Complementary information to data-driven regulatory decision making

As a trigger to a more detailed **investigation via other regulatory pathways**

Significant **challenges** (data quality, ethical considerations, differences of social media platforms, compliance with data protection requirements)

Significant current **limitations** possibly overcome in the future through **technological advances**

Encouraging **researchers** in this field to conduct further studies, as this could help enhance the EU regulatory system and bring about public health benefits

The power to question is the basis of all human progress.

Indira Gandhi

It's better to know some of the questions than all of the answers.

James Thurber

Further information

Heads of Medicines Agencies www.hma.eu
European Medicines Agency www.ema.europa.eu

The European Medicines Agency is
an agency of the European Union

Eleonora Agricola

Innovation and Scientific Advice EMA - Office

AIFA – Italian Medicines Agency

EU Innovation Network

Email: e.agricola@aifa.gov.it

            innovation.office@aifa.gov.it

Social Media data as a part of the evidence toolbox in regulatory decision making

Regulatory Context

Regulatory decision-making processes:
EMA Committees and Working Parties

Setting for Data Generation

Controlled Setting

Clinical Trials (Protocol)

Real World Setting

Clinical Care (routine)

Daily Life (Voluntary)

Data Collection Methods

Clinical Data

RWD

Interviews

mHealth Tools

Databases: Claims, EHRs, prescriptions

Biologic materials

CRFs

Questionnaires & Surveys

Systematic Review/ Meta analysis

Registries

Social media

Type of Social Media (Real World) Data

Individual Specific Patient Data

User Profile   Username, Age, Gender, Followers/Friends,…

User Posts   Text, video or imagery

Post Metadata   Time stamp, location, …

Non-individual specific Data

Post Metrics   Amount of Views, Likes, Comments, Shares, Reposts,…

Responses   User comments; text, video or imagery