23rd DGRA Annual Congress

Industry perspective on the current regulatory climate

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Agenda

- ***COVID learnings:*** Ways of working, opportunities for sustained regulatory flexibility, clinical trial advances
- ***Health Authorities Changes and observations:*** EMA, BfArM, DIMDI…
- ***EU Pharma strategy:*** Efficiency, access, digital innovation
- **Opportunities and regulatory leadership:** International collaboration, new modalities, patient engagement

COVID learnings: ways of working, opportunities for sustained regulatory flexibility, clinical trial advances

COVID learnings

Regulators, National health authorities and Industry reacted with an outstanding commitment:

- To speed development of therapies and vaccines
- To support against medicines shortages (EC)
- To create strong COVID 19 guidelines for the field of clinical trials
- To enhance transparency with non-scientific public

National / Regional / International collaboration has been key over these last 18months of pandemic

EMA annual report, available on EMA website

Pandemic aside, some problems were already existing

Example of Clinical Trials challenges, before Covid-19

- 80% of clinical trials faced recruitment problems
- 30% the dropout rate across all trials
- 85% of trials fail to retain a sufficient number of patients
- 70% of potential participants live more than 2 hours away from their nearest study center

Then, COVID-19 happened…

→ Start of the crisis: Up to 90% of CT were delayed

Regulators were quick and open to ideas on how to keep clinical trials going:

EMA Guidance to sponsors on how to manage clinical trials during the COVID-19 pandemic

FDA Guidance on Conduct of Clinical Trials of Medical Products During the COVID-19 Public Health Emergency

*Managing Continuity in Clinical Trials in the COVID-19 environment: The Decentralized Option and Regulatory Flexibility

COVID-19: An accelerator?

	Clinical Trials	Variations	Approval and HTA	Drug shortages
Before COVID	Difficulties to enroll patients	Inefficient life-cycle management	EU disparities	Increasing Supply complexity
After COVID	EU harmonization	Agile regulatory framework	Integrated HTA/HA combined SA	Reduce complexity
	Digital tools	Use of technological advances	Forum on access to health	Mitigate risk on critical medicines
	Decentralized CT	New fees regulation	EUnetHTA	Common EU reporting framework

The COVID-19 regulatory response has been a sandbox for applying new ways of working and collaboration…

… showing potential solutions how to adapt the EU regulatory framework to a more complex, multifaceted world

EU Pharma strategy:
RWE, digital innovation, e-labeling, cloud-based submissions

New Pharmaceutical Strategy for Europe

- *"**Work sharing/collaboration** instead of full geographic representation"*
- *"**Convergence of regulatory requirements** for ATMPs"*
- *"Alignment on the **interpretation of data protection** - create an environment where R&D in genetics can flourish"*
- "***Strengthening all Member State Regulatory Authority expertise** by financing contributions directly from Authorization fees based on the level of quality and resource needs."*

- *"Further strengthen EU's leadership towards **global regulatory convergence** especially as new technologies emerge"*
- *"Ensuring the **acceptance of RWE** in medicines evaluation both pre- and post-authorization"*
- *"Encourage the use of **novel clinical trial** designs"*
- *"**Replace the paper** patient information leaflets with electronic versions"*
- *"Enhance security, transparency and oversight of **supply chains**"*

What would be the benefits of these proposals ?

Real world evidence supporting regulatory approval…

- The use of real-world data (RWD) and real-world evidence (RWE) can provide appropriate data sources and methods for surveillance and analysis

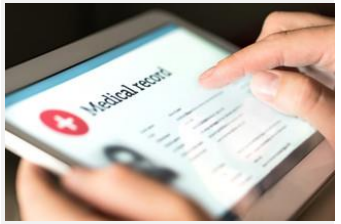
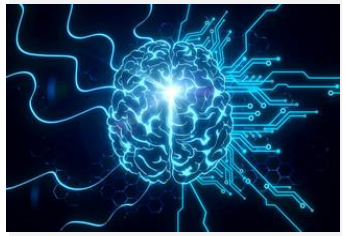
→ Need for Regulatory agencies, HTA bodies and Industry to come together to standardize datasets, data capture, and data analytics

Regulatory submissions and reviews via a globally accessible cloud-based technology platform…

- New approaches to digital and electronic submissions and reporting could become more mainstream, leapfrogging older, less efficient approaches

Reduce the regulatory burden for industry and focus on developing new innovative medicine

Path forward into the future?

Decentralized clinical trials	Digital tools	RWE/RWD	Cloud Based Submissions	Work sharing for approval	E-labelling
					
Reduce barriers to participation	Generate new endpoints	Provide new data sources	Reduce time for approval	Redistribute expertise	Provide the latest information to patients and doctors

HA Changes and observations:
EMA, BfArM, DIMDI…

Vision for future EMA/HMA

All **processes redesigned & reimagined to leverage** 'digital'

Capable of **accepting data plus (or instead of) documents**
→ *Need to move beyond eCTD (20th century concept)*

Data of the **highest quality**, in line with **international standards**, and **reused** seamlessly

The model is **scalable to all other HAs** to ensure that the gain of the digitisation can be reflected across the whole European network

The same transformation as when banking became digital
Highly secure system – easy to use, intuitive

**From EFPIA:EMA Strategy on Digitalisation*
Prepared by: Patrick Middag

*DVPMG: Digitale-Versorgung-und-Pflege-Modernisierungs-Gesetz
**source: vfa

Vision for Germany

Digital initiatives providing local solutions, some national hurdles remain

Digital information – for HCP: option to replace paper distribution is provided by DVPMG* that allows to include DHCP Letter (Rote-Hand-Briefe) and HA approved education material into physician software;

GI 4.0 App – for patients: eProduct-information is available in Germany since April 2020; currently an addition to the paper PIL with potential for more options

National databases: New Drug-Information system (AMIce) since Aug 2020 replacing AMIS – a local solution for Germany; New online portal since June 2021 to inform BfArM/PEI on supply shortages – option to strengthen EU wide distribution of information?

National disconnect: 48% of Marketing authorization-relevant clinical studies were not included in G-BA assessments** – joint advice appreciated

Digitalisation is positive – option for higher transparency in EU and reduction of redundancies

Opportunities and regulatory leadership:
International collaboration, new modalities, patient engagement

International Collaboration of Regulatory Agencies

Advancing international collaboration on RWE to support decision making

EMA to facilitated parallel regulatory review

Further streamline implementation of ICH-guidelines

Based on the data analyzed the median time/to/approval was similar between the FDA and other Orbis partners

How to address in the future EU regulatory network?

- EMA/HMA to strengthen EU's leadership towards global regulatory convergence especially as new technologies emerge (e.g. regulatory requirements for ATMPs) – Need resource allocations

Patient Engagement

Traditional settings
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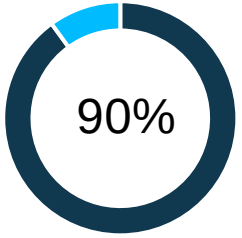
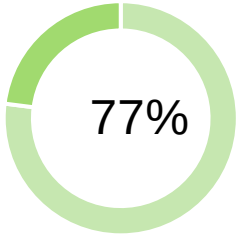
Regular on-site visits with personal interactions

Doctors and nurses



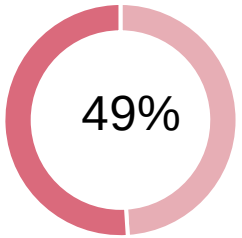
find interaction with Health Care Professionals helpful

Clearer Information



want easier information about clinical trials

Previous patients



want contact with patients who participated in a clinical trial

Decentralized CT
-
Should not mean dehumanized even with less on-site visits ensure patients wellbeing

Involve

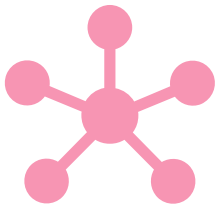
Patients across the drug development lifecycle

Listen

To patient feedback and create new tools and strategies that fit their expectations

Share

Information so that patients understand the goal of the study and know how to use the digital tool



*The Patient Perspective on Clinical Trials: Survey Results and Industry Implications

EMA / EU regulatory network of the future

EMA/HMA to adopt a vision for 2030 permitting to develop new innovative medicines with strategic priorities and redistributed expertise in a more agile structure (removing unnecessary interfaces between EC, EMA &Committees and NCAs)

Going further towards 2030

- ❑ Full conversion to an expert-driven structure, supporting innovations in emerging science
- ❑ Full advantage of virtual settings
- ❑ Creation of a center for medical device
- ❑ Strengthen regulators/HTA collaboration

EUROPEAN MEDICINES AGENCY
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eunethta
EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

“We are shockingly fast when we need to be, so why not be shockingly fast all the time?”