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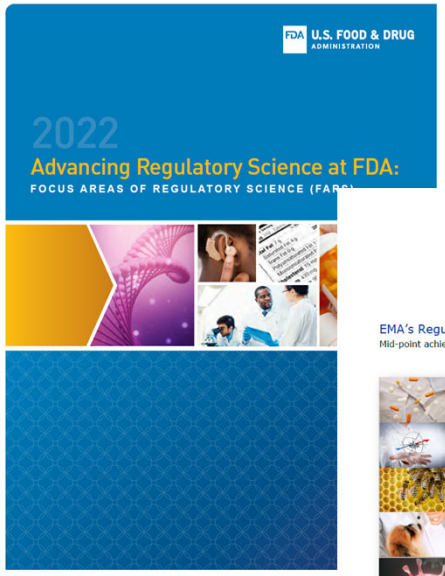
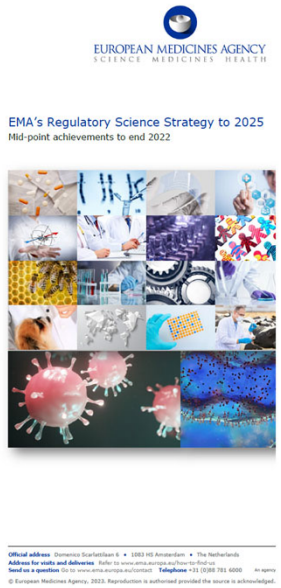
Omologazione del futuro basata sull'evidenza/Regulatory Science

Dott.ssa Eveline Trachsel
Capo settore Omologazione e vigilanza Medicamenti

Come sarà l’omologazione del futuro basata sull’evidenza?





Argomenti prioritari sulla Regulatory Science

Equilibrio tra innovazione e sicurezza delle/dei pazienti

- Orfanizzazione/Real World Evidence
- Digitalizzazione/intelligenza artificiale
- Globalizzazione/coordinamento internazionale
- Equità sanitaria/coinvolgimento delle voci delle/dei pazienti

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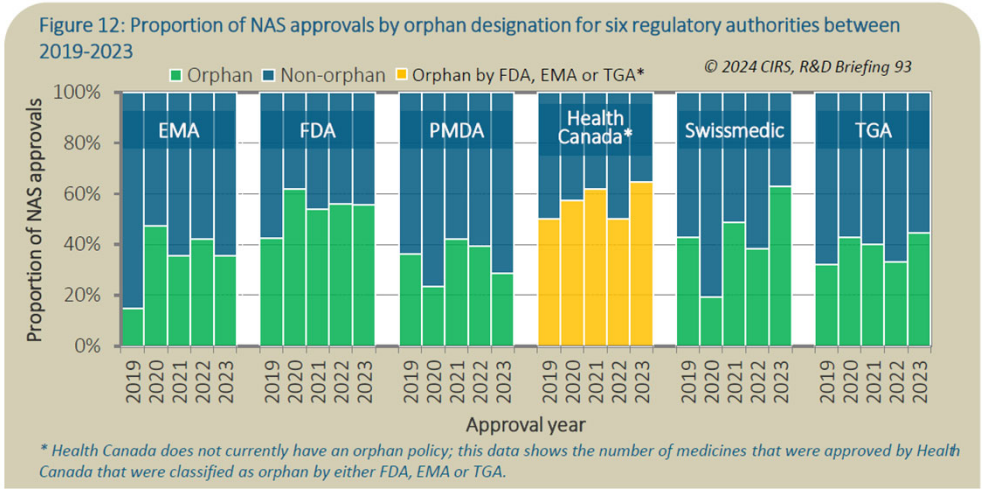
Malattie rare e medicamenti orfani

ICMRA Rare Symposium 16./17.9.24



CIRS R&D Briefing - **New drug approvals by 6 authorities 2014-2023**

5.3 Application for recognition of ODS (Art. 4 – 7 TPLO)

5.3.1 Principle

A human medicinal product is granted the status of important medicinal product for rare diseases (Orphan Drug) on application if the applicant can demonstrate that the medicinal product meets the criteria in accordance with Art. 4 para. 1 letter a^{decies} TPA (Art. 4 TPLO).

The criterion for the rarity of the disease always applies to the disease in its entirety, including all stages of it, and not to an isolated stage in the course of the disease or to a sub-group defined by molecular genetic markers, unless the subgroup is so limited as a result of another medical condition that it is recognised and classified as a separate disease. A sub-group (e.g. Her-2 positive breast cancer) does not qualify as an independent, rare disease; neither, for example, does the restriction of an indication to second-line treatment.

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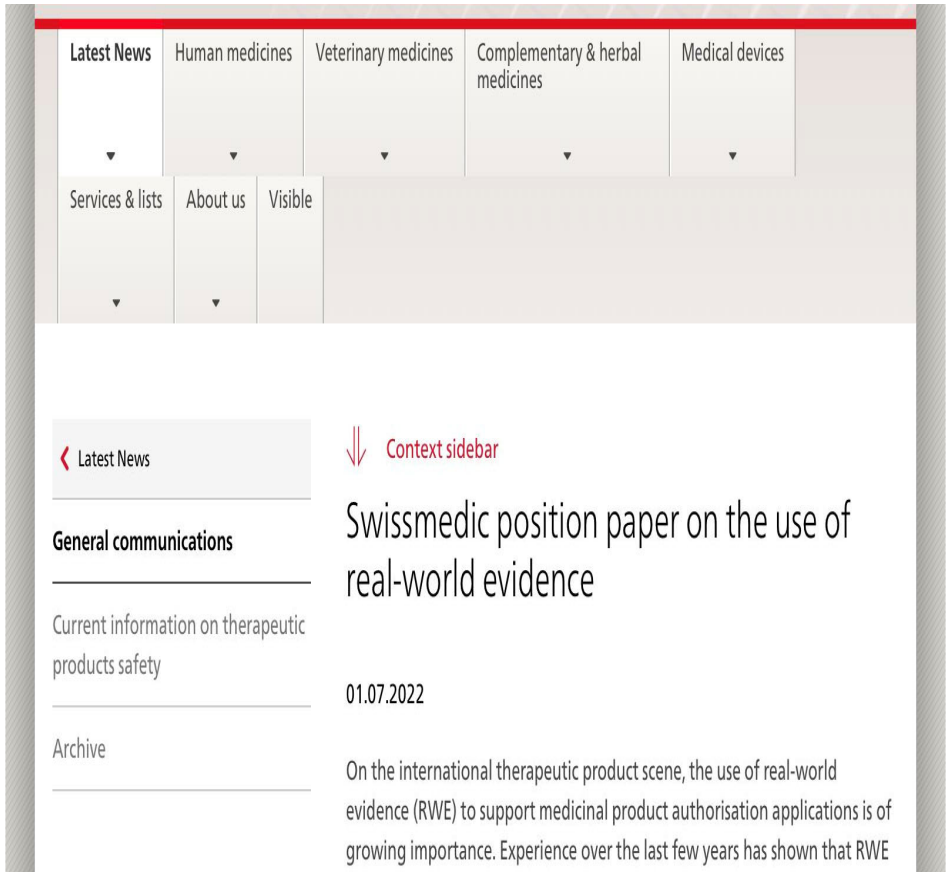
Il documento di posizione RWE descrive la posizione di Swissmedic



Due to the various uncertainties associated with the use of RWD/RWE, detailed descriptions and explanations of the methodology and statistics, predefined in a study protocol, are of particular importance. The following general aspects need to be addressed when planning RWE:

- Definition of the research question(s) and objective(s), including rationale and appropriateness of outcome measures and preferably using the estimand framework (ICH E9(R1))
- Description and justification of the research/study design including a discussion of strengths and weaknesses
- Detailed information on the pertinent RWD sources including data standards applied, coding systems, traceability, quality check procedures and whether the data were collected prospectively or retrospectively
- Definition of the study population using inclusion/exclusion criteria, including a discussion on generalisability
- Statistical Analysis Plan including sample size considerations, detailed description of primary and secondary outcome measures, statistical methods, planned sensitivity and subgroup analyses
- Milestones/timelines such as approval/waiver by ethics committees, data capture (start/end date), data cut-off(s), database lock, planned reporting (interim/final)
- Discussion of anticipated limitations, challenges and potential biases
- Reporting of amendments and protocol deviations

In addition to the critical points listed above, compliance with national and international law and regulations, ICH guidelines, ethical, legal and regulatory standards needs to be ensured.

Appropriate consents and data anonymisation/de-identification techniques are required to ensure compliance with data privacy requirements and must be confirmed to Swissmedic in writing.

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Documento di posizione RWE_EN.pdf

I medicamenti hanno un effetto diverso sulle donne rispetto agli uomini?

Médecine intégrant une approche genre et santé publique :

un plus pour toute la société
12 juin 2024, de 9h15 à 16h30, Berne

Keynote-Session II :
Les différences en matière de diagnostic, de soins et de thérapies

Différences de genre chez les proches aidants de personnes atteintes de démence
Annemarie Schumacher Dimech, responsable du programme CAS Palliative Care, Faculté des sciences de la santé et de médecine, Université de Lucerne (all)

Différences de genre dans le domaine des soins : la prestation de soins intensifs
Atanas Todorov, Scientifique médical , Gebhardlab (all)

Aspects spécifiques au genre dans l'approbation de médicaments
Christine Haenggeli, responsable Clinical Assessment, Secteur Autorisations de mise sur le marché et vigilance Médicaments (fr)

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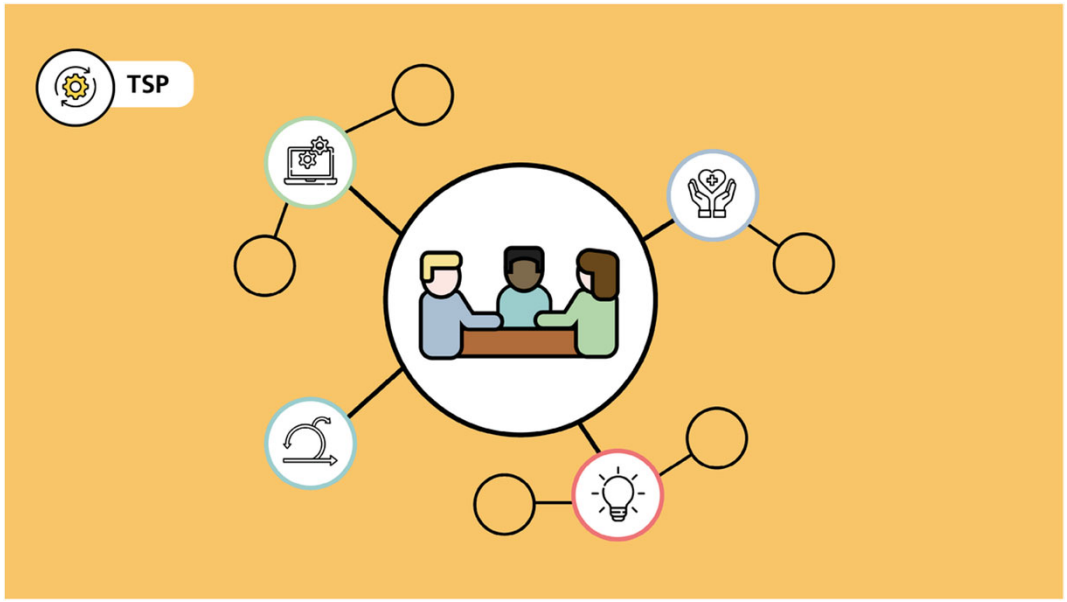
Nuovo membro del comitato di esperti di Swissmedic

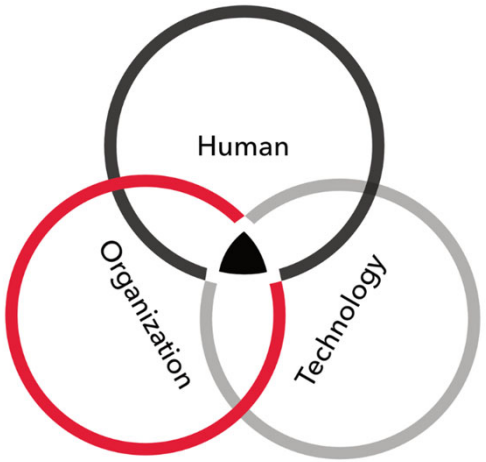
Prof.ssa Dott.ssa Berna Özdemir
Oncologa e specialista di genere, Inselspital

Digitalizzazione e intelligenza artificiale



Intervento di Roger Rüegg

swissmedic 4.0



Intervento di Michael Renaudin