



SPOTLIGHT ON THE CMD PROGRAM: DON'T MISS YOUR CHANCE TO APPLY BY DECEMBER 31ST!

If you're passionate about advancing medicines development, Module 4: Clinical Trials is a must-explore feature of the GMDP Academy's Certification in Medicines Development (CMD) program, in partnership with [King's College London](#). Led by Domenico Criscuolo, MD—an industry veteran with over 50 years of experience—this module dives deep into the evolving landscape of clinical trials. From the ethics of research and Good Clinical Practice to decentralized trials and cutting-edge tools like ePRO, it's a comprehensive guide to this critical field. Click [here](#) to learn more and apply now.

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U.S. RESEARCHERS LAUNCH STUDY ON H5N1 IN NATIONAL MILK SUPPLY

Following the outbreak of H5N1 in dairy cattle, U.S. researchers launched a study to assess the virus's presence in the national milk supply. Dubbed "the silo study," this six-week project, began October 28 and tests Grade "A" raw milk samples from storage silos at dairy facilities in participating states. The double-blind study aims to gather data on H5N1 prevalence without identifying states or facilities involved. Analysis will be done by the USDA's National Veterinary Services Lab, using protocols from the Grade "A" Milk Safety Cooperative Program. This data will support efforts to manage virus spread and monitor any mutations.¹

Continue reading [here](#).



EUROPEAN MEDICINES AGENCY ISSUES GUIDANCE ON SINGLE-ARM TRIALS FOR DRUG APPROVAL



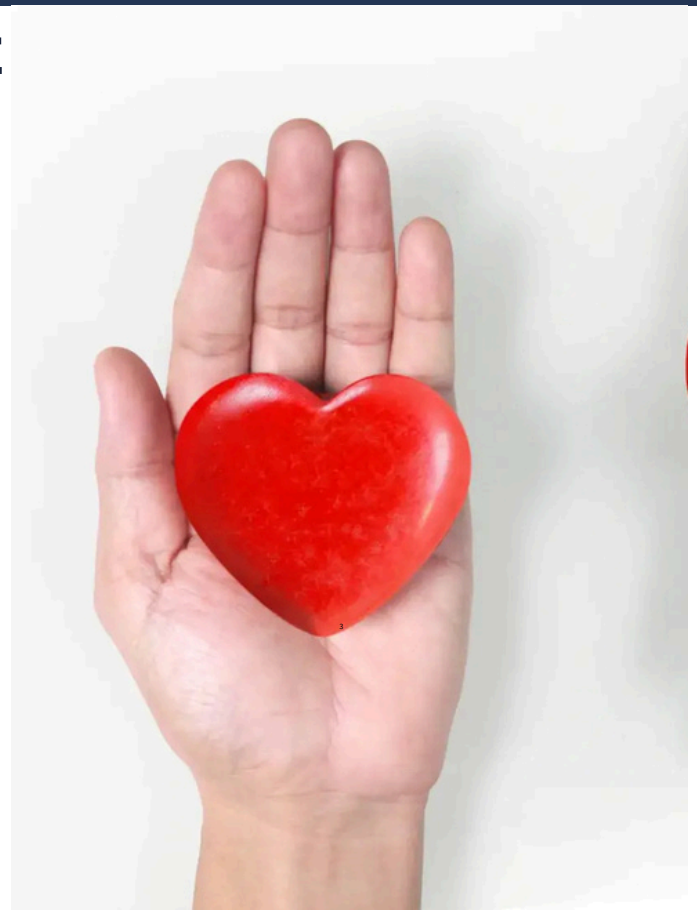
The European Medicines Agency has released a reflection paper on using single-arm trials (SATs) as pivotal evidence in marketing authorization for medicines in the EU. The document, which followed a public consultation, outlines the key considerations and methodological requirements for SATs when submitted as primary evidence in support of drug approval applications.

It focuses on aspects unique to SATs and aims to guide both applicants and regulators in assessing their suitability for regulatory decisions.² Read more [here](#).

GLOBAL ORGAN SHORTAGE AND ETHICAL SOLUTIONS

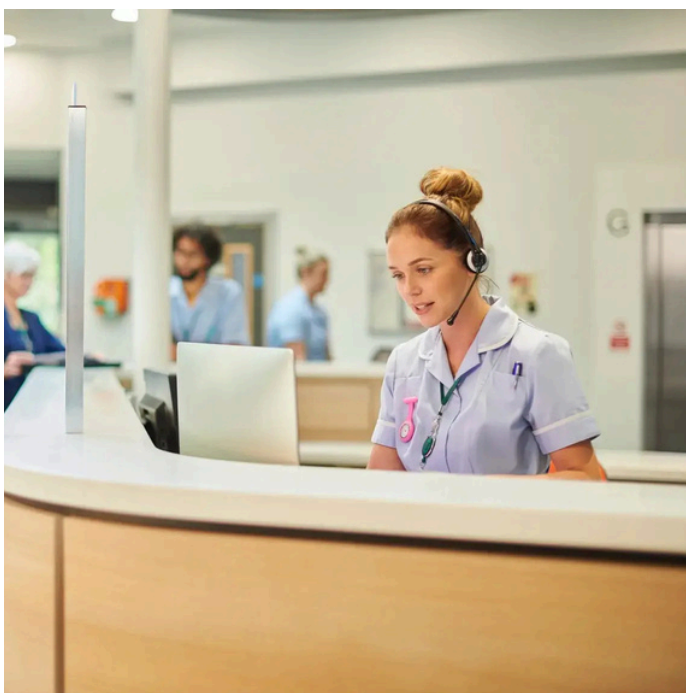
Organ transplantation is often the only viable treatment for end-stage organ failure, yet a global organ shortage persists, with only 10% of demand met. Transplantation rates vary widely, with the U.S. and Spain reaching over 130 transplants per million people, while countries like India see just 12 per million, and many regions lack data or established programs.

This shortage has spurred an illegal organ trade that exploits vulnerable populations. In response, the World Health Assembly passed a resolution in May 2024, led by Spain, to increase organ availability and ensure ethical access. Spain's leadership in organ donation, with the highest deceased donor rate globally, is attributed to its comprehensive legislative framework, clinical leadership, and efficient logistics under the National Transplant Organization (ONT), supported by strong societal backing—a model that may inform practices in other countries.³



Continue reading [here](#).

ACT EU LAUNCHES HELPDESK TO SUPPORT NON-COMMERCIAL SPONSORS IN CLINICAL TRIALS



ACT EU has launched a helpdesk to assist non-commercial sponsors in managing the EU clinical trial process. This helpdesk provides customized technical guidance on the Clinical Trials Information System (CTIS) and clarifies regulatory requirements throughout the clinical trial lifecycle. It can also consult with National Competent Authorities for case-specific support. Non-commercial sponsors can access this service by submitting a ticket through the CTIS Service Desk, identifying their “User affiliation” as non-commercial.⁴

You can register at the CTIS helpdesk [here](#).

WORLD ALZHEIMER'S MONTH 2024: RAISING AWARENESS AND BREAKING STIGMA

World Alzheimer's Month, held each September and led by Alzheimer's Disease International (ADI), focuses on raising global awareness of dementia and addressing stigma and discrimination against those affected. ADI's 2024 campaign aimed to improve understanding and reduce barriers to timely dementia diagnosis and care. Released on World Alzheimer's Day (September 21), ADI's World Alzheimer Report 2024 built on a 2019 survey that set a global benchmark for dementia stigma.

Read more [here](#).



NEWS FROM THE FDA: PROSTATE CANCER INSIGHTS



The FDA published some useful information about prostate cancer, which is the most prevalent cancer among men in the U.S. and the second leading cause of cancer-related death. Risk increases with age, and Black men have the highest incidence and mortality rates. Prostate cancer originates in the prostate gland, and although about 13% of men in the U.S. will develop it, many cases are low-risk and don't need treatment. Key risk factors include age and family history, with a higher risk if close relatives have had prostate cancer or genetic risk factors.⁶

As usual, prevention is the best tool. Read more [here](#).

THE 2024 COHORT IS ALMOST READY TO FINALIZE THE ACADEMIC YEAR AND RECEIVE PROFESSIONAL CERTIFICATION

Pravin Chopra and Jacob Coots, Module Chair and Interim CEO, and Director of Operations respectively, announced the finalization of all academic activities related to Module 6 (“Medical Affairs as a strategic business partner”) with outstanding markings in terms of knowledge gain and satisfaction with the program.

The interim results of the 2024 program are comparable to those from past years, summarized below. A similar report for the 2024 cohort is expected.



Seven annual cohorts, 682 participants from 86 countries were enrolled in the program.



The program was assessed using the classic Kirkpatrick Model, showing elevated levels of satisfaction (over 4.0) on a five-point scale, significant gains in competence at the cognitive level, and leveraged performance.



Notably, 70 % of responding alumni reported significant improvements in their job duties, corroborated by 30% of their supervisors.

We look forward to the Academy continuing to contribute to life-long learning in Medicines Development, addressing educational gaps and fostering interdisciplinary collaboration. Our success highlights the importance of lifelong learning in keeping pace with the industry’s evolving demands and underscores the potential of blended learning in achieving educational objectives in pharmaceutical medicine.

 Don’t Wait – Apply by December 31st for the [2025 CMD program!](#)

GMDP ACADEMY 2024 STUDENT GRADUATION CEREMONY

Join us in celebrating the achievements of our graduates as they take their place among the next generation of leaders in medicines development! This virtual event will honor the hard work and dedication of students who have completed the Certification in Medicines Development program, offered in collaboration with King’s College London.



Jan 28, 2025 at 10:00 AM EST

Click [here](#) to register!

REFERENCES

1. Program, H. F. (2024, November 8). Investigation of Avian influenza A (H5N1) virus in dairy cattle. U.S. Food And Drug Administration. <https://www.fda.gov/food/alerts-advisories-safety-information/investigation-avian-influenza-h5n1-virus-dairy-cattle>
2. Establishing efficacy based on single-arm trials submitted as pivotal evidence in a marketing authorisation | European Medicines Agency (EMA). (n.d.). European Medicines Agency (EMA). <https://www.ema.europa.eu/en/establishing-efficacy-based-single-arm-trials-submitted-pivotal-evidence-marketing-authorisation>
3. Lancet, N. (2024). Organ donation: lessons from the Spanish model. *The Lancet*, 404(10459), 1171. [https://doi.org/10.1016/s0140-6736\(24\)02128-7](https://doi.org/10.1016/s0140-6736(24)02128-7)
4. Home · EMA Account Management. (n.d.). <https://register.ema.europa.eu/identityiq/home.html>
5. Neurology, N. L. (2024). Dementia-related stigma is still pervasive. *The Lancet Neurology*, 23(11), 1063. [https://doi.org/10.1016/s1474-4422\(24\)00404-6](https://doi.org/10.1016/s1474-4422(24)00404-6)
6. Office of the Commissioner. (2024, September 17). Prostate cancer. U.S. Food And Drug Administration. <https://www.fda.gov/consumers/minority-health-and-health-equity-resources/prostate-cancer>

Thanks for reading!

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