



PUBLIC RELATIONS

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WEEKLY EU HEALTHCARE NEWS UPDATE

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EMA ADVICES SPONSORS ON MANAGING THE IMPACT OF THE WAR IN UKRAINE ON CLINICAL TRIALS

On Wednesday (30 March), in view of the disruptions caused by the Russian invasion, the European Medicines Agency (EMA), the European Commission and the Heads of Medicines Agencies (HMA) issued initial advice for sponsors on how to manage the conduct of clinical trials.

European regulators guided sponsors to “use the experience gained during the COVID pandemic” in managing clinical trials affected by the crisis. The advice was requested by study sponsors, who wanted to know how to manage documentation, trial records, data collection and protocol deviations.

Regulators acknowledged that “certain changes and protocol deviations in the current situation are unavoidable when for example scheduled study visits cannot take place, or arrangements need to be made to transfer trial participants who are fleeing Ukraine to other investigator sites of the same trial in the European Union.”

Regulators said the Clinical Trials Coordination Group, an HMA group comprised of clinical trial experts, is also developing recommendations to address specific circumstances linked to the war in Ukraine.

Source: <https://www.ema.europa.eu/en/news/advice-sponsors-managing-impact-war-ukraine-clinical-trials>

RED CROSS HUMANITARIAN AID CANNOT REACH FRONTLINE UKRAINIAN CITIES AND VILLAGES

On Tuesday (29 March) the Director-general of the Ukrainian Red Cross Society, Maksym Dotsenko, pointed out the lack of agreements about the ceasefire, making it impossible for the organization to reach people in need.

The Red Cross network established logistics pipelines from Poland, Hungary, and Romania to allow for the delivery of life-saving aid into Ukraine, supporting the Ukrainian Red Cross Society in areas most saturated with internally displaced persons. Within the past month, Ukrainian Red Cross provided help for more than 400 000 people and assisted in the evacuation of another 80 000. Moreover, the Red Cross administered first aid and delivered more than 2,000 tons of humanitarian aid.

On Thursday (31 March), the International Committee of the Red Cross (ICRC) has confirmed via its Twitter account that its warehouse in Ukraine's Mariupol was targeted in a Russian shelling and revealed that it has not been able to deliver aid due to "the intensity of the fighting" in the besieged city

Source: <https://www.euractiv.com/section/health-consumers/news/red-cross-humanitarian-aid-cannot-reach-ukrainian-cities-where-hostilities-continue/>

WILL THERE BE AN EU-WIDE COORDINATED APPROACH FOR THE SECOND COVID BOOSTER?

During the meeting of EU-27 health ministers in Brussels on Tuesday (29 March), a group of EU countries urged the EU Commission to introduce a coordinated approach regarding the administration of the second COVID-19 booster jab – both in terms of timing and the population to be covered.

According to media reports, Germany and Italy were among the countries advocating for a unified position across the European Union, arguing that inconsistent choices in various EU Member States only result in confusing people, while not helping vaccination campaigns.

Stella Kyriakides, EU Health Commissioner, has informed ministers that the European health agencies are examining all the data and will propose the timely recommendations very soon. She also urged EU countries to remain vigilant, underlining that the vaccination campaign must continue as the pandemic „is still with us“.

Currently, the situation is fragmented as some member states have already started administering the additional booster dose for immunosuppressed patients, while others give this possibility to elderly people, starting from 60 or 75 years old.

Source: <https://www.reuters.com/world/europe/german-health-minister-wants-eu-recommend-fourth-covid-shot-2022-03-29/>

Thank you for your attention!

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