

Clinical Trials during Covid-19 Pandemic

Tri-academic Press Release from French National Academy of Medicine, National Academy of Pharmacy and Academy of Sciences

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To combat the Covid-19 pandemic, the medical community has sought among the available drugs novel therapeutic strategies. However, urgency should not be confused with haste. Scientific rigour cannot be overlooked on the pretext of the seriousness of the situation, nor can the speed of action be at the expense of the quality of the design and implementation. A therapeutic trial responds to methodological rules and to the compliance with deontological and ethical imperatives. The transgression of these principles does not favour the rapid discovery of a treatment. On the contrary, it can lead to confusion which reduces the chances of finding irrefutable therapeutic indications.

For the general public, the binding rules of therapeutic trials may appear cumbersome and unsuitable for patients and their relatives in case of emergency and in the light of medical tragedies. However, the current experience shows the danger of a purely empathic or compassionate approach, as it delays the answer to the question of the efficacy of the tested drugs. The hospital administration has reacted quickly by mobilising its structures for conducting therapeutic trials that have been implemented for several decades. The pandemic has led to the adoption of trial strategies that adapt to the changing clinical situation and allow several therapeutic hypotheses to be tested rapidly at the same time. On the other hand, the lack of coordination, consultation and cooperation of therapeutic trials at national, European and international level is regrettable. This lack of coordination has led to a lack of cooperation which is partly responsible for multiple, redundant, small-scale trials which are likely to be inconclusive.

In both pandemic and ordinary circumstances, the critical assessment rules of methods and results should apply. The same is true of scientific and medical ethics, respect for scientific integrity and the ethics of communicating results.

Recommendations

The National Academy of Medicine, the National Academy of Pharmacy and the Academy of Sciences:

- Recommend a coordination of therapeutic research in France that can strike a balance between competition and cooperation. This can be done under the aegis of national alliances such as the National Alliance for Life Sciences and Healthcare (*Alliance nationale pour les*

sciences de la vie et de la santé) in order to avoid redundancies that scatter patient recruitment and compromise the statistical power of the trials.

- Call for a review of the approval of project procedures and for the strengthening of the expert committee resources: Committee for the Protection of Persons (*Comité de protection des personnes*), National Agency for the Safety of Medicines (*Agence nationale de sécurité du médicament*) to speed up procedures. The access time limits to these committees and the duration of their evaluations are a pretext, in emergency, for circumventing the rules of therapeutic trials.
- Emphasize the need to respect the terms of reference of the Independent Oversight Committees and to refrain from premature disclosure of ongoing clinical trials.
- Call for a coordination of the trials and a standardization of their procedures be established at the European level.