



نقابة صيادلة لبنان
Order of Pharmacists of Lebanon

Towards a National Pharmaceutical Strategy in Lebanon

Appendix A – Strategic Framework and Recommendations to promote Clinical Trials

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The suggested strategic framework to promote Clinical Trials in Lebanon is based on 4 pillars/components that are context-specific:

Supportive environment by giving incentives, promoting public-private coordination, and stronger branding

- Develop a public-private coordination hub for central coordination
- Endorse all national initiatives to promote research and CT in Lebanon
- Give incentives to Higher education institutions (HEIs) to encourage collaboration, support MOPH for the sustainability of the Lebanon clinical Trial registry (LBCTR), support existing and new clinical research organizations (CROs), audit companies, and encourage insurance companies that are needed to cover research participants (to lower prices for example) to overcome lack of funding at the country level
- Develop stronger external branding of existing expertise, technical capabilities of research centers, and the supportive regulatory framework and component authorities, especially among pharmaceutical and medical devices industries

Transparent and efficient Legal/Regulatory Framework for CT by MOPH

- Ensure sustainability of CT Registry through IT portal
- Publicize and disseminate relevant information on CT conducted in Lebanon
- Authorization of ethics committees and certification to CT centers at the hospital level to have a transparent ethical and regulatory system in place
- Setting a regulatory framework to fully protect patients' safety and interests through law without adding a bureaucratic burden on researchers and sponsors
- Re-Establishment of central lab and expansion of pharmacovigilance center
- Support the accreditation of universities labs to obtain Good Laboratory Practices (GLP) and research centers
- Set regulations for clinical trials involving medical devices
- Set regulations for clinical trials involving genetic testing and Bio-banking for research purposes
- Set guidelines for clinical trials involving vulnerable groups (i.e., refugees)

Standardization and Technical Support by WHO

- Collaborate with MOPH and relevant universities for the standardization of all ethical, technical, and administrative processes of CT sites
- Share best practices (GCP, GLP, etc.) and ethical know-how
- Capacity building to have component authorities
- Support training on ethical issues and other relevant topics for IRBs and for researchers

Networking and Collaboration between HEIs

- Organize CT infrastructure at the hospital level to avoid operational barriers (for the delay in approvals of IRBs)
- Build a network of specialized centers (from inside and outside of Lebanon) for collaboration and to create a hosting clinical trials environment



- Build a network of authorized IRBs for unified approval for multi-centers studies
- Build expertise networks and work on human resource development
- Improve access to patients, share information and biological samples
- Develop educational programs tailored to the research team to cover ethical as well as technical aspects to build human capacity
- Commit to all national regulations and guidelines issued by MOPH (trials that involve genetic testing)
- Commit to registering all interventional CTs done in Lebanon at the LBCTR
- Collaborate with MOPH and WHO on the standardization and guidelines for the conduct of CTs
- Increase awareness of patients on the importance of CT
- Proper implementation of the “Ethics Charter and guiding principles for scientific research in Lebanon” that was developed by CNRS
- Reduce the IRB fees and the operations costs

The commitment to implement all of the recommendations mentioned in this document will ensure the application of the highest standards of safety for patients, improving the research environment on a wider scale by setting standards for quality for CT in Lebanon which will benefit patients and will attract a large number of international pharmaceutical companies, medical equipment companies, and researchers to conduct their studies in Lebanon which will have a positive economic impact on the health sector in Lebanon.