Analysis of ANMAT Provision 4008/2017, issue 26 April 2017

- Establishes a **3 working day** period for the Medical Evaluation Department to **verify initial documentation** initially submitted as part of a Clinical Trial Application in Argentina once they receive the initial application (*Article 2*)

- **Provides a 60 working day** technical review period by ANMAT DERM Department for Protocol Evaluation. If DERM has objections the clock will stop until the submitting party provides satisfactory answers or clarifications. Once DERM technical review is completed there will be 10 more working days to issue the corresponding written ANMAT provision with the results of the CTA Evaluation (*Article 1*)

- The timeline for DERM technical review will be reduced to **45 working days** in the case of:
  a) Protocols under execution in at least one of the following countries (Australia, Belgium, Canada, Denmark, Italy, Japan, United States, Sweden, Spain, Switzerland, all those EU members)
  b) Protocol being approved execution in countries that ANMAT considers of Regulatory Convergence and
  c) Protocols approved and under execution in countries recognized by PAHO to have a Regulatory Health Agency of Reference

In all cases once DERM technical review is completed there will be 10 more working days to issue the corresponding written ANMAT provision with the result of the CTA evaluation (*Article 3*).

- (Article 4) in order to prove the study qualifies per Article 3 as describe above the entity submitting application will need to present:
  i. IND Approval by FDA, EUDRACT Approval by EU Agency. Documented Approval issued by other country as listed above
  ii. Declaration from sponsor that study is being implemented in the above mentioned countries

- Specifies that after evaluation period no pending response or comments from any of the parties (Sponsor and ANMAT) Sponsor will be enabled to initiate the study which approval has been requested and request to ANMAT that the technical review report and corresponding approval be issued within **5 working days** (*Article 7*)

- **For sites that work in a jurisdiction with a Centralized Ethic Committee** Accrediting EC´s within the jurisdiction, the documentation for submission of site approval will be limited to Details of investigator, investigational Site an EC. Within 30 days of approval submission of such s Clinical Site the sponsor must submit a certified copy of the approval letter by such EC for investigator to conduct the protocol at the referenced Clinical Site. There will be no changes in documentation requirem*ents investigators at sites in other jurisdictions (Article 5, Amendment to item 2.2 of 6677/2010 regulation*)

- If during the initial Evaluation of Study the sponsor submits an Amendment, the technical Review by ANMAT DERM will be suspended (*Article 6*).