Review

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| Reviewer A  2018-02-05 11:11 AM  For author and editor | Subject: Post Trial Access in Clinical Research: A Hallmark of Its Relevance To Bioethics and Current Clinical Research and Ethical Guidelines   * The article does not capture author's perspective or experience. It is just a summary of guidelines. * Author's focus is limited to PTA of new drug only. It is desirable to discuss the PTA issues from diverse perspectives e.g. benefits to control group / community, access to technolgy tranfer / standrd therapy etc and issues specific to vaccines, triials of generics etc. * Author's also should discuss practical issues for PTA arising out of time gap betwween trial completion and confirmation of efficacy/safety and regulatory approval/restrictionns on import of unapproved new drugs in India. * Some statements appear to be misleading e.g. * When an investigational drug or intervention is identified as beneficial in a clinical trial, participants must receive PTA, as it’s denial in vulnerable subjects could be lethal. * Folowing statement from Declaration of Helsinki (DoH) - participants enrolled in clinical trials must receive access to experimentally proven efficacious drug - is not correct- does not appear in DOH 2013. * Author's should discuss Indian scenario for PTA and suggest solutions. |
| Reviewer A  2018-02-05 11:11 AM  For editor | Subject: Post Trial Access in Clinical Research: A Hallmark of Its Relevance To Bioethics and Current Clinical Research and Ethical Guidelines   * The article does not capture author's perspective or experience. It is just a summary of guidelines.   Mala Comments: I think the reviewer is reiterating that a commentary should include the author’s perspective and that is sadly lacking. We need to send the comments to the authors asking them to address these. |