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FDA Issues Draft Guidance for Clinical Trial Imaging Endpoints

The Food and Drug Administration (FDA) has issued a draft Guidance for Industry on “Standards for Clinical Trial Imaging Endpoints.” The purpose of the draft Guidance is to assist sponsors in the use of imaging endpoints in clinical trials of therapeutic drugs and biological products. Sponsors can use these standards to ensure that the imaging data is maintained within and among clinical sites, and that there is a verifiable record of the imaging process. This guidance describes procedures recommended for interpreting and collecting medical images in efficacy trials. However, it does not address whether or not specific measurements are clinically meaningful and are acceptable for drug approval

<http://interactive.snm.org/docs/Draft%20Guidance%20for%20Clinical%20Trial%20Imaging%20Endpoints1.pdf>



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