

References for NCIC CTG New Investigator's Course Presentation by Scott Laurie

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Greaves P, et al. First dose of potential new medicines to humans: how animals help. *Nature Reviews Drug Discovery* 3: 226-236, 2004

ICH guidelines: <http://www.ich.org/products/guidelines/safety/article/safety-guidelines.html>

Suntharalingam et al. Cytokine storm in a phase I trial of the anti-CD28 monoclonal antibody TGN1412. *New England Journal of Medicine* 355: 1018-1028, 2006

Dayan CM and Wraith DC. Preparing for first-in-man studies: the challenges for translational immunology post-TGN1412. *Clinical and Experimental Immunology* 151: 231-234, 2008

Objectives for the talk:

Prerequisites for Therapeutic Studies in Humans

1. To briefly review the drug development process to ensure everyone is familiar with the terms
2. To review the preclinical components that are required to be included in an IND submission
 - * Pharmacology: mechanism of action, PD
 - * Pharmacokinetics
 - * Efficacy studies
 - * Safety pharmacology
 - * Animal toxicology
 - * Determination of the safe starting dose for phase I