


I. ICH GCP 1.50 – Serious Adverse Events (SAE) or Serious Adverse Drug Reactions (Serious ADR)

<p>What are the requirements for an adverse event to be considered a Serious AE (SAE) or a Serious ADR?</p>	
<p>Serious AE/ Serious ADR</p>	<p>Any untoward medical occurrence that at any dose:</p> <ul style="list-style-type: none"> <input type="checkbox"/>* Results in death, <input type="checkbox"/>* Is life-threatening <input type="checkbox"/>* Requires inpatient hospitalization or prolongs an existing hospitalization <input type="checkbox"/>* Results in persistent or significant disability/incapacity <p>or</p> <ul style="list-style-type: none"> <input type="checkbox"/>* Is a congenital anomaly/birth defect