

Goals / Definition

Conduct Summative Human Factors Study and compile final results.

This test validates that the device, product or system is safe, effective and usable by the all intended user groups. It differs from the formative test in that now you have to use a device that represents exactly the device that is going to be launched to the market.

CRITERIA	SAMPLE CONTENT REQUIREMENT	GUIDELINES FOR LEVEL OF DETAIL NEEDED AT EACH GATE
<ul style="list-style-type: none">Summative Human Factors study completed	<ul style="list-style-type: none">a) Provide evidence of safety and efficacy of the drug-device combination product – from use by representative intended users, under realistic use conditions, for essential and high-risk tasksb) Observe and record errors and/or failures using objective and subjective measuresc) Collect user opinion and feedback, particularly related to use problems	