

Goals/ Definition

Develop a set of user needs that can be ultimately translated into device requirements.

User needs capture what the device does or should do and acceptability of those needs across different geographies.

CRITERIA	SAMPLE CONTENT REQUIREMENT
<ul style="list-style-type: none">Intended use, User capabilities and preferences assessedEthnographic studies and user needs conducted	<ol style="list-style-type: none">Assessment of use case, user needs, capabilities, and acceptance (user needs often cannot be finalized before TPP creation) developed within delivery workstreamAssessment of market and healthcare ecosystem (procurer requirements (incl. costing considerations), provider, governmental support, etc.) developed within delivery workstreamEthnographic studies to evaluate the care setting, cultural factors, and other factors associated with intended application and settingTask analysis as a precursor to human factors engineering