

Interactive Voice Response (IVR) Solutions for Common Pharmaceutical Clinical Trials' Problems

Problems	IVR Solutions
<ul style="list-style-type: none"> ▪ Diary data collected on paper forms result in incompleteness and retrospective completion ▪ <i>Sleep and sleepiness studies</i> 	<ul style="list-style-type: none"> ▪ All IVR calls are date and time stamped, so adherence cannot be faked ▪ Individual and overall study adherence can be tracked in real time ▪ <i>IVR Pittsburgh Sleep Quality Index (PSQI) and IVR Stanford Sleepiness Scale (SSS)</i>
<ul style="list-style-type: none"> ▪ Many standardized assessments require complex branching or are difficult to present to all subjects in a consistent manner ▪ <i>Depression severity</i> ▪ <i>Assessment of comorbid conditions</i> 	<ul style="list-style-type: none"> ▪ IVR assessments are administered in the same manner for every subject, eliminating inter-rater differences resulting in unbiased measures of change ▪ <i>IVR Hamilton Depression Rating Scale (HAMD) or IVR Hospital Anxiety and Depression Scale (HADS)</i> ▪ <i>Mental Health Screener (MHS)</i>
<ul style="list-style-type: none"> ▪ Subjects may be reluctant to discuss sensitive, personal issues with site staff ▪ <i>Sexual functioning</i> 	<ul style="list-style-type: none"> ▪ With sensitive subjects (both individuals and topics), individuals find it easier to provide information to the computer, are more honest with the computer, and prefer the computer to human raters ▪ <i>IVR Changes in Sexual Functioning Questionnaire (CSFQ)</i>
<ul style="list-style-type: none"> ▪ Seeing subjects daily is seldom feasible but when done, increases confounding therapeutic effects ▪ <i>Onset of efficacy</i> ▪ <i>Pain assessment</i> 	<ul style="list-style-type: none"> ▪ IVR minimizes the nonspecific therapeutic effect of contact with site staff and provides a means for gathering additional improvement data between visits, at minimal cost ▪ IVR systems are available 24 hours a day, 7 days a week, and subjects can easily make calls from their own homes without traveling to study sites ▪ <i>IVR Six Questions on Depression (6QD)</i> ▪ <i>IVR McGill Pain Questionnaire</i>
<ul style="list-style-type: none"> ▪ Time critical assessments outside usual office hours ▪ <i>Description of each BM in IBS</i> 	<ul style="list-style-type: none"> ▪ IVR assessments are convenient for subjects and staff ▪ <i>IVR IBS Monitoring System</i>