CONDUCTING TRIALS REMOTELY VIA TELEHEALTH

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AMC+Health
eVisits

Clinical Study Personnel

- Authenticate Pt ID
- eCOA Clinician Assessments
- Instruct
- Observe & Engage
- Receive Alerts
- Push Reminders
- Secure Text Messaging
- Q&A

Study Participant

- ePRO / Surveys
- Collect vital signs
- Perform tests
- Protocol & Rx Reminders
- Track progress
- Engage
- Schedule
- Q&A
Supporting eVisits

Sensor Device Integration

Database
Mobile App

Care Console
Telehealth Platform

Process Design / Rptg

Logistics
Training & Support

Part 11 Compliant Platform
FDA Approved Class II Device
PATIENT CENTERED EXPERIENCE

E-Visit

First Time In Experience
Journal Entry
E-Message
Measures History

AMC Health
Episodic vs. Continuous Data

- Clinic Visit
- Home Reading
- eVisit
# Selected Studies of Telehealth

<table>
<thead>
<tr>
<th>Therapeutic Area</th>
<th>Multiple Sclerosis</th>
<th>Parkinson’s Disease</th>
<th>Ulcerative Colitis</th>
<th>Prostate Cancer</th>
<th>Alzheimer’s Disease</th>
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<tbody>
<tr>
<td><strong>Patient Convenience</strong></td>
<td></td>
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<td></td>
<td>At local Primary Care Physician</td>
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<tr>
<td>At home</td>
<td>At home</td>
<td>At home, and local GI Office</td>
<td>At home</td>
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<td><strong>Study Efficiency</strong></td>
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<td>Local GI Practices</td>
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<td>13 Satellite Sites</td>
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<td><strong>Recruitment</strong></td>
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<td>Large urban coverage</td>
<td>Statewide coverage</td>
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<td>Statewide coverage</td>
<td>Nationwide coverage</td>
<td>Statewide coverage</td>
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<tr>
<td><strong>Data - Quality, Speed, Qty</strong></td>
<td>Modified MSFC</td>
<td>Motor and non-Motor Assessments</td>
<td>Images</td>
<td>Observation and Rx Compliance</td>
<td>Demonstrate Equivalence</td>
</tr>
</tbody>
</table>
Telehealth in Multiple Sclerosis

Structure
- Phase II
- Single Site Study
- 80 Subjects at Home
- 12/14 eVisits
- Statewide Reach
- Patient and Caregiver

Measures
- eVisit
- BP & Weight
- Wearable - Gait
- ePRO
- Modified MSFC
- Walk, Peg Bd, Pasat
- MSQOL, FSS

Objectives
Feasibility of motor and non-motor assessments
Reliability and value of eVisits
Telehealth in Parkinson’s Disease

Structure
- Single Site Study
- 40 Subjects at Home
- 5 eVisits
- National Reach (9) – Ph III
- Patient and Caregiver
- Sub study – Phase III

Measures
- eVisit
- BP & Weight
- ePRO
- MDS UPDRS / MOCA
- Columbia Suicide
- Med Compliance

Objectives
1. Feasibility of motor and non-motor assessments
2. Reliability and value of eVisits
Telehealth in Ulcerative Colitis

Structure
- Statewide reach; Local GI
- 4 virtual visits (nutritionist, PI)
- e-Consent

Measures
- eVisit
- BP, HR, Temp, Wt
- Remote Nurse Visit (labs)
- e-Food Diary
- PSCCAI – Patient ePRO

Objectives
1. Feasibility of a Nutritional CAID Diet
2. Reliability and value of eVisits

Frequent diarrhea
Sudden constant feeling to move bowels
Blood in stool
Reduced appetite
Weight loss
Fever
Abdominal pain
Fatigue
# Prostate Cancer

## Structure
- Single Site Study
- 15 Subjects at Home
- 5 eVisits
- Statewide Recruitment
- Patient and Caregiver
- Sub study – Phase III

## Measures
- eVisit
- Medication Compliance
- Quality of Life Questionnaire

## Objectives
- Feasibility of conducting a eVisits in patients with prostate cancer and a rising PSA post local therapy.
- Safety
- Treatment adherence
- Changes in PSA
- Patient satisfaction
- Quality of life

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**Bone pain that doesn’t go away or leads to fractures**

**Numbness or pain in the hips legs or feet**

**Burning or pain during urination**

**Loss of bladder control**

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# Telehealth in Early Alzheimer’s Disease

## Structure
- 1 Central Site – Neurologist Rater
- Mult. “Satellite” PCP Sites
- 30 Subjects Cross-over design
- Statewide
- Patient and Caregiver

## Measures
- eVisit
- ePRO
- Manual Assessments Uploaded

## Objectives
Reliability that data collected from an eVisit is reliable and of comparable data quality VS an in-person study visit

![Image of an elderly woman and a young woman](image)

- Confusion with time or place
- Difficulty completing familiar tasks
- Challenges in planning or solving problems
- Memory loss that disrupts daily life

[AMC+H logo]
## Value of eVisits

### eVisit Benefits

<table>
<thead>
<tr>
<th>1</th>
<th>Improve Patient Connectivity: Recruit &amp; Retain More Subjects</th>
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<tbody>
<tr>
<td>▪ Speed recruitment by expanding patient reach to those living far from study site</td>
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<tr>
<td>▪ Improve retention by reducing patient time &amp; travel burden</td>
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<tr>
<td>▪ Engage and inform subjects with mobile app, text</td>
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<table>
<thead>
<tr>
<th>2</th>
<th>Improve Data Quality: Obtain More Robust &amp; Actionable Data</th>
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<tbody>
<tr>
<td>▪ Send data to study team in near-real-time</td>
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<td>▪ Improve protocol adherence and drug compliance</td>
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<td>▪ Improve patient safety monitoring and oversight</td>
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<tr>
<td>▪ Correlate other robust data (activity, sleep, diet, mood) to improve quality of submissions</td>
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<th>3</th>
<th>Improve Study Efficiency: Reduce Duration and Cost of Study</th>
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<tr>
<td>▪ Faster recruitment shortens study duration</td>
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<td>▪ Improved retention reduces study size</td>
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<td>▪ Improved workflow at the clinical research site</td>
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<td>▪ Eliminates transcription errors</td>
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<td>▪ Supports Fast-Fail approach</td>
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In deploying telehealth studies:

- Consider patient condition/needs
- Begin early in protocol development stage
- Cater technologies that support/not hinder
- Validate measures for the remote environment
- Design the output