Dig deep to find added value

Philips Motion Assay Services reveal data insights
When you perform a clinical trial, you record your subject’s height and weight and you take a blood sample as part of a well-designed study. We suggest you add a motion sample to this routine. A motion assay may be valuable for learning about each subject’s response to therapy.

Philips Motion Assay Services are designed to reveal specific and objective information about how a drug or treatment is impacting your patient’s daytime activity and sleep patterns. We use high-resolution actigraphy and advanced signal processing to extract more valuable data from your motion assay. It can capture the small pauses and disturbances that are not always reflected in conventional endpoints but may be important in understanding the effects of therapies.

Why novel endpoints?
You may be familiar with conventional endpoints based on measurements of motion such as Activity METS, Total Sleep Time, Steps Per Day and Wake After Sleep Onset (aWASO). We believe that there is more information available in motion data than is presently being extracted. Identification of novel motion endpoints based on objective analysis may be more sensitive to the effects of your treatment, thereby providing new insights. To maximize results, we can advise you at study outset as to what endpoints are most suited to your area of research.

Key Advantages
Extract valuable information to measure your subject’s sleep and activity patterns through the use of advanced signal processing and novel endpoints.

- May identify drug effects otherwise undetectable with conventional analysis methods.
- Explore data prospectively and retrospectively to better understand study results
- Profit from the value of stored data as new algorithms are developed to extract useful information.

Figure 1.
Example of a Novel Endpoint: Shannon Entropy (a measure of information content)

Subjects with similar activity levels during REST can have different Entropy values

![Graph showing Shannon Entropy values for Healthy and OA Pain subjects.]

Entropy differences are seen in larger groups of Healthy and OA Pain subjects

Subjects with osteoarthritis (OA) Pain have greater Entropy values during REST than healthy subjects - even though mean REST Activities levels are similar:

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Activity</th>
<th>Entropy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthy</td>
<td>56</td>
<td>13.6 ± 9.4</td>
<td>1.52 ± 0.38</td>
</tr>
<tr>
<td>OA Pain</td>
<td>42</td>
<td>16.3 ± 5.1</td>
<td>2.01 ± 0.81</td>
</tr>
</tbody>
</table>

p-value >0.10 <0.001

Entropy may reflect an important aspect of pain not revealed by conventional actigraphy analyses.
While actigraphy data is usually collected in studies of sleep and sleep disorders, there are many more disease states that may benefit from such objective analysis – such as COPD, Alzheimer’s, Rheumatoid Arthritis, Parkinson’s, Fibromyalgia and Bipolar Disorder.¹

**Powerful data analysis tools**
What makes our services unique? We’ve developed tools to automatically separate the rest period from the active period using a proprietary algorithm that processes the times series signal in datasets of any size. Once the data are partitioned, we apply signal-processing analyses on the rest and active periods to derive new and useful endpoints. These novel endpoints are often exploratory at first but their value may grow as their physiological meaning becomes well established with additional studies.

This advanced signal processing is potentially very beneficial. The algorithms are effective in reviewing large amounts of data quickly to identify specific mathematical features. These features may provide evidence of a measureable effect of a compound or treatment. *(See Figure 1.)*

**Collect the data – use it anytime**
It is important to collect the information-rich motion data in each subject, and fortunately that is easily done. You may use any number of wrist-worn actigraphy devices. Guided by protocol advice from our team, you typically collect one to two weeks of baseline data, followed by administration of your drug, and one to two additional weeks of data collection.

Upon conclusion, we download and analyze the data and present you with your novel endpoint values. If any questions remain, or study results are equivocal, additional motion assays can be run retrospectively on the stored data. You do not have to repeat the study. We can also go back to historical data and perform advanced signal processing methods to extract new information from past studies. This is a very cost effective opportunity to help increase your confidence in drug development decisions.

As we assist customers with targeted motion assay analysis, we continue to develop a versatile repertoire of novel endpoints that are available to you as part of our Motion Assay Services.

**Philips Motion Assay Services include the following:**

**Protocol Advice**
We work with your team to establish novel endpoints to use for your particular clinical trial.

**Motion Data Collection**
We distribute and service various motion recording devices, obtain data from these devices and store the data for later analysis, or send you the data files.

**Rest-Activity statistical measures**
We analyze the data (provided by Philips and/or other devices) using our Advance Signal Processing tools to perform statistical measurements that describe the pattern of motion in the rest and activity periods. This output is in a format that is usable to you.

**Consultation and Guidance**
If needed, we provide post-study consultation to help interpret the significance of the results and provide guidance on additional analyses that may be helpful.
