

Vendor selection



considerations for
clinical trial design
utilizing digital
measurement of
nocturnal scratch

NOCTURNAL SCRATCH



Digital Measures Development

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A project by the



What aspects should I assess when selecting a technology vendor for my trial?



For more in-depth information refer to the following resource:

HealthXL: [Digital Health Vendor Assessment for Clinical Trials](#)

- Category 1: General organizational operation and products
- Category 2: Quality Management Principles
- Category 3: Practices of product or service design
- Category 4: Device supply and provisioning, import & export
- Category 5: Account provisioning
- Category 6: Study specific materials (investigators)/design/usability
- Category 7: Live trial support for stakeholders
- Category 8: Trial closeout activities
- Category 9: (GDPs) Data handling/processing and data flow
- Category 10: Device and Data (sensors + raw data) algorithm accessibility for review
- Category 11: Interoperability/Integration
- Category 12: Validation/Clinical Relevance/standard of documentation to showcase
- Category 13: Cybersecurity

Important aspects to consider when selecting a technology vendor

as identified by Nocturnal Scratch Measurement Deployment working group

- ✓ Validation & verification of device and algorithm in place
- ✓ Ability to support multiple countries
- ✓ Established quality management system
- ✓ Preserved confidentiality of collected patient data
- ✓ Direct technical support to the study sites
- ✓ Processes in place for shipping and returning of devices
- ✓ Assurance of maintained data integrity and quality upon transfer and rest
- ✓ GCP compliance
- ✓ Sufficient number of devices available for the trial needs
- ✓ Provision of training & use manuals for the device for the site & the patient
- ✓ Robust development, scientific and manufacturing quality practices:
 - Good manufacturing practice (are all devices from the same and different manufacturing batches providing the same result measurements?)
 - Good product development practices (for both hardware and software - e.g., is the software lifecycle documented and monitored for quality? Can software or firmware updates interfere with the measurement or data processing? Have the algorithms been tested with appropriate datasets? etc.)
 - Good scientific practices

Specific inquiries for vendors of technologies measuring nocturnal scratch



What measurements does the device offer?

- **Minimum requirements:** Detection & quantification of scratching movement (alternatively, raw accelerometer output in data quality applicable to use with a selected scratch detection algorithm, if the algorithm is not part of the device in question)
- **Desired threshold:** Sleep measurement
- **High quality threshold:** Environmental factors (light, temperature, etc.), vitals (heart rate, skin temperature, blood oxygenation, etc.)

Does the device come in contact with skin in everyday use?

- If yes, what parts of the body does it come in contact with?

What material is the device and its parts made of?

- Please describe the used materials, such as adhesives, bands, metallic elements, etc.
- Has the device been tested for irritation and sensitization? (e.g. according to ISO 10993-10:2010)

Specific inquiries for vendors of technologies measuring nocturnal scratch



In what age range, ethnic groups and other specific population groups can this device be used?

- Has it been tested for use in adult patients?
- Has it been tested for use in children?
- Has it been tested for use in people of different skin colors?

Can the device be used during sleep time without disturbing the sleep of the patients?

- For example, light from sensors, vibrations, notifications, etc.

Can using lotions or other topical skin treatments impair the measurement performance?

- If yes, what parts of the body does it come in contact with?

Does the device need to be taken off during the daytime/non-sleep period, or can it be worn continuously?

Have there been any device usability evaluations conducted to evaluate human factors of device use?



Relationships matter.

Here's how to establish a positive relationship between the study sponsor & technology vendor.

Sponsors should engage with vendors early in study design to tailor the needs between technology capabilities, data requirements, & patient needs and preferences

Benefits for all

Though the vendor is usually responsible for device verification & analytical validation, collaboration with sponsors and other stakeholders on clinical validation will be beneficial for all parties. A collaboration on clinical validation among stakeholders can help establish:

- Desired validation thresholds for technology performance
- Specific needs of target clinical populations
- Acceptability and usability of technologies in target clinical populations

Creation of open-access datasets or publishing methods is another approach to advance overall innovation in the space beyond single trials or sponsor-vendor relationships

Benefits for vendors

Since technology vendors usually don't have direct access to patients, enabling a feedback loop to share lessons, challenges, and experiences from patients back to vendors with the assistance of sponsors can create an avenue for improvement in technology for specific target populations

Benefits for sponsors or researchers

For sponsors and researchers, it is often crucial to analyze sensor-level data. Providing access to high-fidelity and sensor-level data creates avenues for research and use of the sensors in novel ways or to assess additional aspects of patient's health (e.g. sleep behavior)

Additional Relevant Resources



- The Playbook: [Worksheet to identify vendor/sponsor responsibilities](#)
- HealthXL: [Digital Health Vendor Assessment for Clinical Trials](#)
- CTTI: [Recommended Strategies for Optimizing Data Quality](#)
- CTTI: [Selecting Mobile Technologies for Data Capture in Clinical Trials](#) (Page 7: Data Collection, Analysis, and Interpretation)

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