

## Case Example: Verification and Validation Processes in Practice

The processes of **verification** and **validation** are complementary but independent from one another. This is illustrated, in part, by the example of a recently developed neural network algorithm to detect scratching movement from an accelerometry signal, where the technology was produced by one company, and the algorithm was developed and validated by another.

A verified accelerometry technology was used to collect the data required for development of the scratching algorithm. The technology manufacturer made verification information available in a peer-reviewed publication that summarized **accuracy**, **precision**, and **uniformity**. The company that developed the scratching algorithm did so by training a neural network using “ground truth”<sup>\*</sup> scratching data from overnight infrared video recordings.

Adults with atopic dermatitis and healthy controls wore an accelerometer on each wrist during the overnight monitoring period, and the video files were manually scored to identify scratching movements of the hands, wrists, and arms. Cross-validation methodology was used to assess performance of the algorithm, and efforts to validate the algorithm further in an independent sample are currently underway. Consistent with CTTI recommendations (see “Reference” box below), a description of the neural network development methodology and algorithm validation has been published in a peer-reviewed journal.

The advantage of separating technology verification and algorithm validation is that the scratching algorithm can process data from any high-quality, tri-axial accelerometer that records data in units of acceleration ( $m/s^2$  or  $g$ ) of a specified minimum frequency (in this case, at least 20 Hz)—as long as it meets or exceeds the **verification** data provided by the manufacturer of the technology used to develop the algorithm.

### Reference: Relevant CTTI Considerations

*For additional considerations pertaining to verification and validation, please reference [CTTI Recommendations for Testing a Digital Health Technology](#).*

- The appropriateness of the selected digital technology should be justified through **verification** and **validation** processes. (Click [here](#) for more)
- Establish industry-wide standards to drive the successful scaling and more rapid acceptance of clinical trials using digital technologies for data capture. (Click [here](#) for more)

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<sup>\*</sup> “Ground truth” refers to information provided by direct observation (i.e. empirical evidence) as opposed to information provided by inference.