

TITLE PAGE

A systematic review of feasibility studies promoting the use of mobile technologies in clinical research

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1 **ABSTRACT**

2 Mobile technologies such as smartphone applications, wearables, ingestibles, and implantables,
3 are increasingly used in clinical research to capture study endpoints. On behalf of the Clinical
4 Trials Transformation Initiative, we aimed to conduct a systematic scoping review and compile a
5 database summarizing pilot studies addressing mobile technology sensor performance, algorithm
6 development, software performance, and/or operational feasibility, in order to provide a resource
7 for guiding decisions about which technology is most suitable for a particular trial. Our
8 systematic search identified 275 publications meeting inclusion criteria. From these papers, we
9 extracted data including the medical condition, concept of interest captured by the mobile
10 technology, outcomes captured by the digital measurement, and details regarding the sensors,
11 algorithms, and study sample. Sixty-seven percent of the technologies identified were wearable
12 sensors, with the remainder including tablets, smartphones, implanted sensors, and cameras. We
13 noted substantial variability in terms of reporting completeness and terminology used. The data
14 have been compiled into an online database maintained by the Clinical Trials Transformation
15 Initiative that can be filtered and searched electronically, enabling a user to find information
16 most relevant to their work. Our long-term goal is to maintain and update the online database, in
17 order to promote standardization of methods and reporting, encourage collaboration, and avoid
18 redundant studies, thereby contributing to the design and implementation of efficient, high-
19 quality trials.

20 **KEY WORDS**

21 Mobile, wearable, sensor, verification, validation

22

23 **INTRODUCTION**

24 An increasing number of clinical trials are being designed in which mobile technology -
25 including smartphone applications, wearables, ingestibles, implantables, and other mobile
26 platforms containing sensors - are being used to capture data of interest to trial stakeholders.¹⁻⁴
27 Rapidly evolving technology within the last several years has allowed for more powerful
28 algorithms (software) to convert the data that are detected by the sensors (hardware) into
29 clinically meaningful endpoints (outcomes).⁵ For example, technology worn at the wrist might
30 include an accelerometer, and various algorithms may then be applied to the acceleration signal
31 to generate estimates of total sleep time, steps per day, and other endpoints. In addition to
32 digitizing existing endpoints, mobile technologies can be used to develop novel endpoints.
33 Potential advantages of trials that adopt mobile endpoints include: real-time data capture and
34 analytics; less frequent study visits; the ability to capture day-to-day variability by collecting
35 data continuously; the availability of objective endpoints to complement patient- and clinician-
36 reported outcomes; increased measurement precision and therefore smaller samples; and the
37 ability to collect data that are more likely to reflect habitual, real-world experiences of trial
38 participants.⁶⁻⁸
39 Although mobile endpoint collection may have several potential advantages, guidance is needed,
40 such as the new framework issued by the U.S. Food and Drug Administration (FDA) to promote
41 development of digital tools
42 (<https://www.fda.gov/NewsEvents/Newsroom/FDAInBrief/ucm626166.htm>) for investigators to
43 make decisions about which technology is most suitable for a particular trial, and what
44 methodology ensures trials are conducted as efficiently as possible.^{9,10} The Clinical Trials
45 Transformation Initiative (CTTI), a public-private partnership between Duke University and the
46 FDA, has recently issued four sets of recommendations and resources intended as a

47 comprehensive guide to improving clinical trial quality and efficiency through appropriate use of
48 mobile technology. Topics covered include the development of novel endpoints; design and
49 implementation of decentralized trials; the application of mobile technology in clinical trials; and
50 the optimization of mobile clinical trials engaging patients and sites ([https://www.ctti-
52 clinicaltrials.org/programs/mobile-clinical-trials](https://www.ctti-
51 clinicaltrials.org/programs/mobile-clinical-trials)). One strong CTTI Mobile Technology
53 recommendation is for investigators to conduct small feasibility/pilot studies before launching a
54 clinical trial, with the overall aim of reducing risk by assessing sensor accuracy, developing
55 and/or validating algorithms, optimizing data quality, identifying unanticipated challenges,
56 exposing weaknesses of the selected system, enhancing participant experience, and satisfying
57 user engagement. To catalogue the breadth of feasibility studies and facilitate the use of these
58 data to enable the development of clinical trials that will use mobile technologies, we conducted
59 a systematic scoping review of the literature, with the overall goal of compiling a living database
60 of feasibility studies. In doing so, our objectives were to promote standardization of feasibility
61 methods; encourage collaboration among investigators and sponsors working in this area;
62 demonstrate the value of feasibility data publication; and avoid the development of redundant
63 studies. The online database derived from the data identified in this review is intended to
64 support the efficient and effective adoption of mobile technologies in clinical research by
65 creating a single, searchable, up-to-date resource that gives users easy access to existing
66 knowledge. The objectives of this paper are therefore to describe the methodology of our
67 systematic scoping review, summarize key trends that emerged from the identified studies, and
68 discuss future directions for maintenance of an online database of feasibility studies designed to
advance the science and ultimately the adoption of mobile endpoints.

69 **RESULTS**

70 *Screening*

71 Our initial search retrieved 3,466 references (see Figure 1). We excluded over half of the
72 retrieved references ($n=2,186$) after title screening, and abstract screening eliminated a further
73 63% ($n=802$). The majority of excluded publications were either not conducted in a defined
74 therapeutic area, or not conducted in a defined participant population. A total of 478 publications
75 were included in the full text review, during which we excluded 203 publications on the basis of
76 our inclusion criteria. Data were extracted from the remaining 275 publications.

77 *Data Categorization*

78 Just over half of all included studies were in neurology or musculoskeletal therapeutic areas,
79 with pulmonary, sleep, endocrine, cardiovascular, and pediatrics making up another 30%
80 combined. Algorithm development was the most common objective (236 studies), followed by
81 sensor performance (133 studies), operational feasibility (126 studies), and software
82 development (24 studies). The median number of participants per study was $n=33$ (range 1-625),
83 with larger samples evident in studies focused on cardiology, neurology, and musculoskeletal
84 disorders. Two ‘*n-of-1*’ studies¹¹ were identified (one in nephrology, one in neurology).

85 Some studies used more than one research tool, such that the 275 studies included 321
86 technologies. Sixty-seven percent of the technologies were wearable sensors, such as actigraphy,
87 smart-watches, smart-clothing, chest-straps, adhesive patches, and Holter monitors. The
88 remaining tools included tablets and smartphones, implanted sensors such as continuous glucose
89 monitors, and cameras. We did not identify any studies using ingestible sensors. Tablets and
90 smartphones were used in a variety of ways; for example, data captured passively via the

91 embedded accelerometer, and active data capture via an app such as finger-tapping or
92 psychomotor vigilance tasks. Within each of these categories, a wide array of make/model tools
93 were studied, each differing in terms of their sampling frequency, filtering, data processing, and
94 compatible software programs.

95 In some cases, missing data precluded a full understanding of some studies and this would likely
96 impact reproducibility. Important gaps include the software used for analysis (73% complete),
97 the comparator measure (83% complete), the make and model of the technology (93%
98 complete), and the age and gender of participants (91% and 85%, respectively). All papers
99 reported the number of participants and the type of technology used, although there was
100 substantial variation in the way that sensors were listed in each paper (for example, ‘motion
101 sensor’, ‘accelerometer’, ‘tri-axial accelerometer’). Several papers listed a non-specific term
102 such as ‘pedometer’ without specifying the actual sensors contained within. Rather than attempt
103 to impose an interpretation, our database lists the technology as reported within the source
104 publication.

105 A static database of all extracted data is accessible via Table e2 (online supplement) with full
106 study references including a digital object identifier (DOI); however, we encourage readers to
107 access the online version that will be updated regularly as more studies emerge ([http://feasibility-
108 studies.ctti-clinicaltrials.org](http://feasibility-studies.ctti-clinicaltrials.org)). The current layout and features of the online database are shown
109 in Figure 2. In addition, the papers that we excluded are listed in Table e3. The online version
110 of the database can be filtered and searched electronically, enabling a user to find information
111 most relevant to their work.

112 **DISCUSSION**

113 In this paper, we describe the methodology underlying our systematic scoping review of
114 feasibility studies focused on mobile technologies. We also summarize key trends that emerged
115 when compiling our searchable database, such as the fact that although some tools we identified
116 (such as Holter monitors and actigraphy) have been used in research and clinical settings for
117 decades, other tools (such as smart-clothing and adhesive patches) are more recent
118 developments, emphasizing that there is still much to learn about different methods of deploying
119 mobile sensors. We noted an absence of standards in both the use of mobile technology in
120 research as well as reporting methodology, evidenced by the lack of consistency across
121 publications which made data extraction challenging. The development of methodology and
122 reporting standards, although beyond the scope of our current project, would be extremely
123 beneficial for the field. The scope and content of our database demonstrates that the deployment
124 of mobile technology in research is an active, growing area of interest to investigators.
125 Information gleaned from our database can not only be used by sponsors to inform trial design,
126 but may also be useful to regulatory bodies such as the FDA, technology manufacturers,
127 engineers and data scientists, patient groups, institutional review boards and ethics panels,
128 statisticians, health policy planners, and clinicians. Further, the ability to access data from
129 feasibility studies readily is likely to facilitate incorporation of mobile endpoints into settings
130 other than clinical trials, such as observational or interventional health outcomes studies¹²,
131 translational research¹³, and eventually, clinical care¹⁴.

132 Although specific objectives differed across the publications we identified, in general all studies
133 aimed to determine whether a specific technology and/or outcome assessment was “fit for
134 purpose”; that is, whether the system was capable of generating the necessary data in a stated
135 context of use. Many studies addressed one or both of the following sets of questions: A) what

136 physical construct is intended to be measured (e.g. movement), what sensor is required to capture
137 those data (e.g. an accelerometer), and how accurate are the sampled data (e.g. intra- and inter-
138 sensor variability of the acceleration signal when compared against a mechanical shaker with
139 known acceleration); *and/or* B) how are the data converted to a meaningful endpoint (e.g.
140 development of an algorithm that converts an acceleration signal into an estimate of total sleep
141 time) and how does the endpoint perform against a comparator (e.g. the agreement between
142 algorithm-generated sleep data with polysomnography-generated sleep data)? The former set of
143 questions address the concept of verification and relate to intrinsic capabilities of the sensor,
144 whereas the latter address the concept of validation and relate to the application of sensor-
145 derived data to health concepts in human participants. A more thorough explanation of these
146 concepts is included in the CTTI “Advancing the Use of Mobile Technologies for Data Capture
147 and Improved Clinical Trials” recommendations ([https://www.ctti-
148 clinicaltrials.org/sites/www.ctti-clinicaltrials.org/files/mobile-devices-recommendations.pdf](https://www.ctti-clinicaltrials.org/sites/www.ctti-clinicaltrials.org/files/mobile-devices-recommendations.pdf)).
149 Other feasibility studies in our dataset addressed considerations such as ease of use, participant
150 comfort, security and integrity of data transfer or storage, and software development.
151 We did not attempt to create data fields indicating study quality or exclude papers that did not
152 achieve a certain quality threshold for several reasons. Firstly, there is tension between study
153 quality and reporting quality¹⁵, and we were only in a position to evaluate what has been
154 reported. Secondly, we concluded that all of the data we sought to extract were valuable, and
155 that highlighting missing data and variability in reporting would provide an opportunity for
156 investigators in the field to reflect on these issues when preparing future manuscripts. Thirdly,
157 the study quality assessments typically used in other systematic reviews may not be appropriate
158 for feasibility studies. For example, in an algorithm development study aiming to capture steps,

159 the sample size is the number of steps, not the number of participants, although larger participant
160 sample sizes remain important to capture variability and ensure generalizability.^{7,8} In our
161 opinion, it is beneficial to focus on whether a particular feasibility study is useful, rather than
162 whether it is of sufficient quality, although there is likely a wide overlap across these concepts.
163 To that end, we recommend the development of levels of evidence, which may help define what
164 is reported in feasibility studies and will therefore make them more useful to others in the field.
165 Thus, in the absence of methodological and reporting standards, we leave it to end-users to
166 explore the database and compare and contrast what they see with ‘best practices’ as outlined in
167 the CTTI Mobile Technology recommendations ([https://www.ctti-](https://www.ctti-clinicaltrials.org/projects/mobile-technologies)
168 [clinicaltrials.org/projects/mobile-technologies](https://www.ctti-clinicaltrials.org/projects/mobile-technologies)).

169 One noteworthy area of missing data was the absence of thorough descriptive information
170 regarding study participants. We aimed to capture only what would be considered the most basic
171 demographic information – age and gender/sex – and noted that these variables were missing in
172 9% and 15% of publications, respectively. Many of the publications in our database were
173 published in journals that typically have an engineering focus; however, all involved data
174 collection in human participants. Although we do not have quantitative data available as we did
175 not aim to extract it, we can attest that many publications captured in our search did not report
176 important participant characteristics such as race/ethnicity, measurements of body habitus,
177 measurements of socioeconomic status, or descriptions of disease severity. The use of mobile
178 technology in clinical studies, particularly those adopting a ‘bring your own device’ model, may
179 impose barriers to participation in underrepresented/underserved populations, and therefore we
180 encourage investigators to assess and report the sociodemographic characteristics of study
181 participants, and consider issues of equity and equality during the study design phase.

182 There are some limitations to our approach that should be noted. Bias may have been introduced
183 by missing relevant literature, given our choice of PubMed as the bibliographic database to
184 search, search terms, and inclusion criteria, particularly given the inconsistencies in terminology
185 across papers. In particular, it is possible that Layer #1 in Table e1, which ensures that a
186 publication refers to some kind of sensor that can be attached to a human participant, may have a
187 slight bias towards technical/engineering authors who may refer to the underlying technology, as
188 opposed to more clinically-focused authors who might in some cases use a single term such as a
189 manufacturer name, a device name, or a generic term such as “activity monitor” for wearable
190 technology containing an accelerometer. We attempted to investigate other sources of bias in
191 our search terms; for example, we performed a sensitivity analysis whereby the word ‘pilot’ was
192 removed from our search terms, and found that fewer than 5% of eligible publications were
193 missed by doing so. Some methodological decisions may have resulted in the exclusion of
194 papers outside of our scope that some readers might find particularly useful, such as studies
195 conducted entirely in an inpatient or clinical setting, or those published before 2014. Our
196 decision to limit the search to publications from 2014 onwards was because our aim was to
197 assemble a resource that reflects the current state of the art. The contents of the database are
198 limited to those feasibility studies published in the peer-reviewed literature, and we acknowledge
199 that relevant data may also exist in the gray literature, in conference proceedings, or in internal
200 reports used by investigators to inform their own future studies and therefore not published at all.
201 In the future, we hope to develop functionality for the online database so that users can put
202 forward potentially relevant publications that we have missed, as well as unpublished reports.
203 The use of mobile technologies for data capture is an evolving and rapidly-expanding field.
204 CTTI plans to update the literature search annually. This process may require changes to our

205 search terms and data extraction methodology as technology progresses. On a quarterly basis, we
206 will also examine relevant publications that we receive from users of the database that we had
207 missed, to see how our search terms or inclusion criteria might be modified to capture similar
208 publications in the future. Our hope is that the growing interest in this field as well as the
209 demonstrated success of using mobile technology in clinical research, will lead to a more
210 standardized lexicon as well as relevant medical subject headings (MeSH terms,
211 <https://meshb.nlm.nih.gov/>) terms that could be assigned to eligible publications, making it easier
212 to find them in future searches. Eventually, if investigators in the field find the online resource
213 useful, journals could encourage or require that authors include all data fields and upload their
214 manuscript to the database, akin to the registration and reporting of clinical trials. Although
215 beyond the scope of the current work, a registry would allow for linking different studies and
216 trials that have adopted the same technology, as well as providing information as to the
217 successful use of mobile technologies in drug approval and/or use in clinical practice.

218 In conclusion, we have created a freely accessible, online database of feasibility studies assessing
219 the use of mobile technologies for data capture, intended to be a valuable resource for many
220 stakeholder groups including researchers, ethicists, regulatory bodies, and patient groups. One of
221 our objectives was to create a user-friendly database that investigators in the field can explore as
222 they make decisions regarding which technology would be most useful for a particular research
223 study, although it should be emphasized that clinical relevance is only one part of the decision-
224 making criteria. The CTTI Mobile Technology recommendations provide information on other
225 important topics to consider beyond sensor verification and algorithm validation, such as cyber
226 security, patient preferences, and data rights ([https://www.ctti-clinicaltrials.org/programs/mobile-](https://www.ctti-clinicaltrials.org/programs/mobile-clinical-trials)
227 [clinical-trials](https://www.ctti-clinicaltrials.org/programs/mobile-clinical-trials)). We hope that the online database resulting from our systematic scoping review

228 reported here becomes a widely-used tool, thereby promoting standardization of methodology
229 and reporting, and contributing to the design and implementation of high-quality, efficient trials.
230

231 **METHODS**

232 *Conduct of the Systematic Scoping Review*

233 On June 21, 2018, CTTI conducted a systematic search of peer-reviewed literature indexed in
234 PubMed and published between January 2014 and May 2018. We did not restrict the scope of
235 our search to any single therapeutic area or mobile technology. A multi-stakeholder team of
236 clinical, academic, technical, operational, and patient experts developed the search terms (listed
237 in Supplementary Table 1 of the online supplement), inclusion criteria (Table 1), and selection of
238 data to be extracted from the final publications (Table 2). A medical librarian supported the
239 development of the search terms.

240 Following the PubMed search, we conducted a multi-step review process to select publications
241 for inclusion. First, two of four trained analysts (AB, EB, CM, KW) independently reviewed
242 each publication title against the inclusion criteria, following the PICOS¹⁶ (Population,
243 Intervention, Comparison, Outcome; Study Design) framework. Second, two of the four analysts
244 reviewed the abstracts of the remaining, potentially eligible publications to determine whether
245 each met our inclusion criteria. When there was disagreement between two reviewers during
246 either phase, the decision whether to advance a publication was resolved by a third analyst.
247 Finally, two analysts reviewed the full text of each of the publications that passed the abstract
248 screening stage, with a third used to settle any disagreements and establish the final list of
249 publications for inclusion.

250 To build the database, four analysts (AB, EB, CM, KW) extracted the data and categorized each
251 publication as described in Table 2. Each publication was assigned to one or more of the
252 following categories: sensor performance; algorithm development; operational feasibility; and
253 software development. The following data were extracted from each: medical condition (used to

254 identify therapeutic area); concepts of interest captured by the mobile technology (for example,
255 sleep); specific outcomes captured by the digital measurement (for example, total sleep time);
256 comparator used to assess the digital measurement (for example, polysomnography); information
257 relating to the sensor/s (for example, accelerometry and photoplethysmography); details related
258 to the algorithms or software (if applicable); and descriptive data for the study sample. After the
259 data were extracted from each publication, it was standardized by two analysts (JG and CM).

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265
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273

274 **DATA AVAILABILITY STATEMENT**

275 All data generated or analyzed during this study are included in this published article (and its
276 supplementary information files).

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278 **AUTHOR INFORMATION**

279 Reprints and permissions information is available at www.nature.com/reprints.

280 ***Competing Interests***

281 JB: full time employee at Philips; JG: full time employee at monARC Bionetworks; MC: no
282 conflicts of interest to declare; AC: full time employee and shareholder at Elektra Labs; AF: no
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293

294 **AUTHOR CONTRIBUTIONS**

295 Conception/design – All authors; Data collection – AB, EB, CM, KW, JG; Data analysis and

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- 346

347 **FIGURE LEGENDS**

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349 **Figure 1: Preferred reporting items for systematic reviews and meta-analyses (PRISMA)**
350 **flow diagram**

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352 **Figure 2: A screenshot of the online database depicting the current layout and features**

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355 **TABLE LEGENDS**

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357 **Table 1: Inclusion criteria adopted to enable the identification of suitable feasibility studies**

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360 **Table 2: Data fields extracted from identified feasibility studies**

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362 **Supplementary Table 1: PubMed search terms used in the systematic review**

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365 **SUPPLEMENTARY DATA**

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367 **Supplementary Data 1: Static feasibility study database**

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369 **Supplementary Data 2: Excluded publications**

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Table 1: Inclusion criteria adopted to enable the identification of suitable feasibility studies

Pre-review	Reported results of original data collection (for example, meta-analyses, editorials, letters, opinion pieces, and methods papers were excluded).
Population	<p>Collected data from human participants (for example, studies that reported results of a computer simulation were excluded).</p> <p>Stated a specific therapeutic area.</p> <p>Defined a participant population that either:</p> <ol style="list-style-type: none"> a. Included participants from the target population <i>or</i>; b. Included participants that would be generalizable to the target population.
Intervention	<p>Included at least one mobile technology meeting our definition for objective outcome (efficacy or safety) data capture.</p> <p>Defined the specific technology used.</p>
Comparator	Specified a comparator (sensor performance and algorithm development studies only).
Outcome	<p>Evaluated mobile technology/ies capturing objective outcomes data (for example, studies examining ePROs¹ as the primary technology were excluded).</p> <p>When mobile technology/ies were used as a therapeutic intervention, the study reported outcomes data.</p>
Study Design	<p>Described a feasibility study in line with our definition; specifically, a feasibility study addresses one or more of the following components:</p> <ol style="list-style-type: none"> a. Performance of an outcome of interest against a comparator where the outcome of interest could be related to: <ol style="list-style-type: none"> i. Measurement performance of sensor <i>and/or</i>; ii. Algorithm performance (clinical endpoints); b. Human factors considerations (acceptability, tolerability and usability); c. Participant adherence; d. Completeness of data. <p>Captured data outside of a clinical setting <i>or</i> captured data in an inpatient or clinic setting specifically to enable out-of-clinic use.</p> <p>Reported data from a participant sample (for example, case studies were excluded; however, n-of-1 studies¹² were considered in scope).</p> <p>Country of origin is reported to have ‘high’ or ‘very high’ human development by the United Nations Human Development Index, http://hdr.undp.org/en/composite/HDI.</p>

¹ ePRO = Electronic patient-reported outcome

Table 2: Data fields extracted from identified feasibility studies

Field	Definition	Allowed Values
Title		Free text
Authors	Last name, initials	Free text
Journal	Name	Free text
Year		2014, 2015, 2016, 2017, 2018
DOI	Digital object identifier. A unique alphanumeric string used to identify content and provide a persistent link to the manuscript's online location.	Free text
Category	The type of study according to the authors' objectives.	Sensor performance, Algorithm development, Operational feasibility, Software development
Therapeutic area	A knowledge field that focuses on research and development of treatments for diseases and pathologic findings, as well as prevention of conditions that negatively impact the health of an individual.	Selected from a list of FDA approved drugs by therapeutic area, https://www.centerwatch.com/drug-information/fda-approved-drugs/therapeutic-areas , with 'pre-natal' included as an additional therapeutic area.
Medical Condition	An abnormal state of health that interferes with normal or regular feelings of wellbeing.	Free text
Concept of Interest	The aspect of an individual's clinical, biological, physical, or functional state, or experience that the assessment is intended to capture (or reflect).	Free text
Outcome Assessment	The measurable characteristic that is influenced or affected by an individuals' baseline state or an intervention as in a clinical trial or other exposure.	Free text
Comparator Measure	The measure used to benchmark the digital measure against.	Free text
Technology	A description of the sensor casing and modality as experienced by the participant.	Adhesive patch, Camera, Chest strap, Continuous glucose monitor, Holter monitor, Implantable, Smart clothing, Smart phone, Smart shoe, Smart watch, Tablet, Wearable, Wearable sensor array.
Sensor(s)	The component of the technology that detects or measures a physical property and records, indicates, or otherwise responds to it.	Free text
Make, Model Manufacturer	The make, model and manufacturer of the technology.	Free text
Wear location	Where the technology is positioned on the participant's body.	Free text
Algorithm / Analysis Software	Name and version.	Free text
Sample size	Total number of participants in the feasibility study.	N
Participant age	Infants <1year Children 1-10 Adolescent 11-17 Adult 18-64 Older adult 65+	Infants, Children, Adolescents, Adults, Older adults
Participant gender	Gender or sex.	Male, Female, both, unknown

IDENTIFICATION

Articles identified through PubMed Search 1/1/2014 – 5/31/2018 (n=3,488)

Out of scope articles excluded (n=22)

- 3 not in English
- 13 books/book chapters
- 5 studies conducted in developing countries
- 1 published in 2013

SCREENING

Titles screened (n=3,466)

Duplicates or irrelevant titles excluded (n=2,186)

Abstracts screened (n=1,280)

Abstracts excluded (n=802)

- 257 not conducted in therapeutic area
- 216 not conducted on a defined participant population
- 77 did not include mobile technology/did not specify technology used
- 73 used the mobile technology as a therapeutic intervention without capturing any outcomes data
- 81 data captures clinical setting only
- 44 methods papers/meta-analyses or systematic reviews
- 32 were not feasibility studies
- 14 case studies/computer simulations/editorials
- 8 did not capture objective outcomes data

ELIGIBILITY

Full-text articles assessed for eligibility (n=478)

Full-text articles excluded (n=203)

- 51 not conducted in therapeutic area
- 49 not conducted on a defined participant population
- 41 data capture clinical setting only
- 24 relied on clinician for data capture
- 9 methods papers/meta-analyses or systematic review
- 8 were not feasibility studies
- 6 did not include mobile technology/did not specify technology used
- 6 used mobile technology as an intervention
- 5 did not capture objectives outcomes data
- 4 case studies/computer simulations

INCLUDED

Articles included in data extraction (n=275)

Figure 2: A screenshot of the online database depicting the current layout and features

The screenshot displays the CTTI Feasibility Studies Database interface. At the top left is the CTTI logo with the text 'FEASIBILITY STUDY INTERACTIVE DATABASE'. Navigation links include 'How It Works', 'Who Should Use', 'Resources', and 'Submit a Paper'. The main header reads 'CTTI Feasibility Studies Database'. Below this is a search bar with 'Search the Database' text and buttons for 'Filter', 'Clear', and 'Download'. A filter selection box contains various checkboxes for columns to display, such as Title, Authors, Journal, Year, DOI, Category, Therapeutic Area, Medical Condition, Concept of Interest, Outcome Assessment, Comparator Measure, Technology, Sensor(s), Device Make and Model, Wear Location(s), Algorithm / Analysis Software, Sample Size, Participant Age, and Participant Gender. Below the filter box, a message states: 'The following 275 publications are feasibility studies on mobile clinical trials. Customize with Search and Filter, and then download your results.' A table of results follows, with columns for Title, Year, Therapeutic Area, Concept of Interest, Technology, Device Make and Model, and Sample Size. Three rows of data are visible.

Title	Year	Therapeutic Area	Concept of Interest	Technology	Device Make and Model	Sample Size
Quantifying the relative change in physical activity after Total Knee Arthroplasty using accelerometer based measurements More Info	2017	Musculoskeletal; Orthopedics/Orthopedic Surgery; Rheumatology	Physical activity patterns; Physical activity	Wearable	ActiGraph, GT1M	32
Predicting seizures from local field potentials recorded via intracortical microelectrode arrays More Info	2016	Neurology	Seizure prediction	Implantable	Blackrock Microsystems, NeuroPort	1
A Wearable Magneto-Inertial System for Gait Analysis (H-Gait): Validation on NormalWeight and Overweight/Obese Young Healthy Adults More Info	2017	Musculoskeletal; Overweight/Obesity	Gait	Wearable sensor array	ATR Promotions, TSDN121; AICHI STEEL, AMI306; InvenSense, MPU-6050	22

Screenshot of the CTTI Feasibility Studies Database, available at <http://feasibility-studies.ctti-clinicaltrials.org>.