

Focused Ultrasound Case Study

FDA Approved Indications Timelines

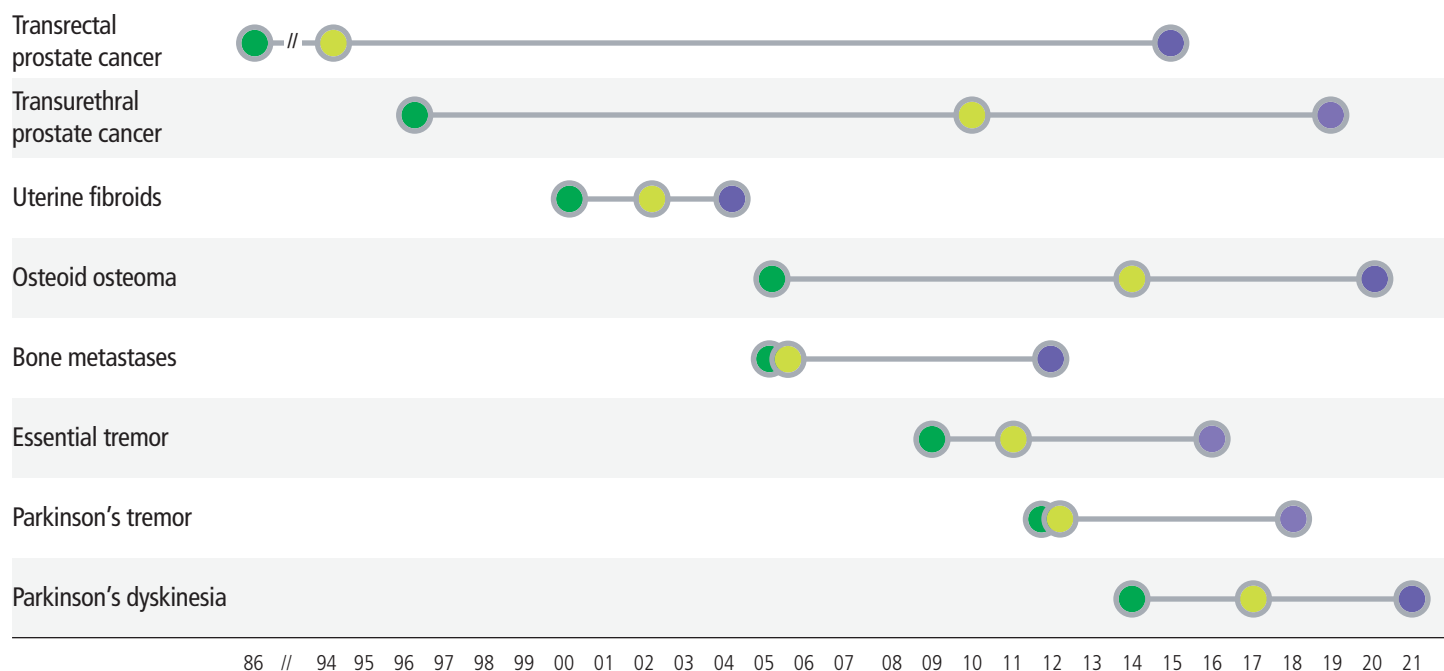


This year we worked with manufacturers to create a timeline from conceptual idea for an indication to FDA approval. When the technology was developed for treating the prostate, the use of focused ultrasound was truly innovative, and it took nearly three decades to go from idea to FDA-approved treatment. The indications to follow took considerably less time, with the more recent indications taking less than a decade. Essential tremor; Parkinson's disease, tremor; and Parkinson's disease, dyskinesia were approved in 7 or 8 years. The summary graph above provides a simplified overview of the timeline. A detailed timeline follows, as provided by the manufacturers for each of the FDA-approved indications

FDA Approved Indications Timeline

■ Concept ■ 1st-in-human ■ FDA approval

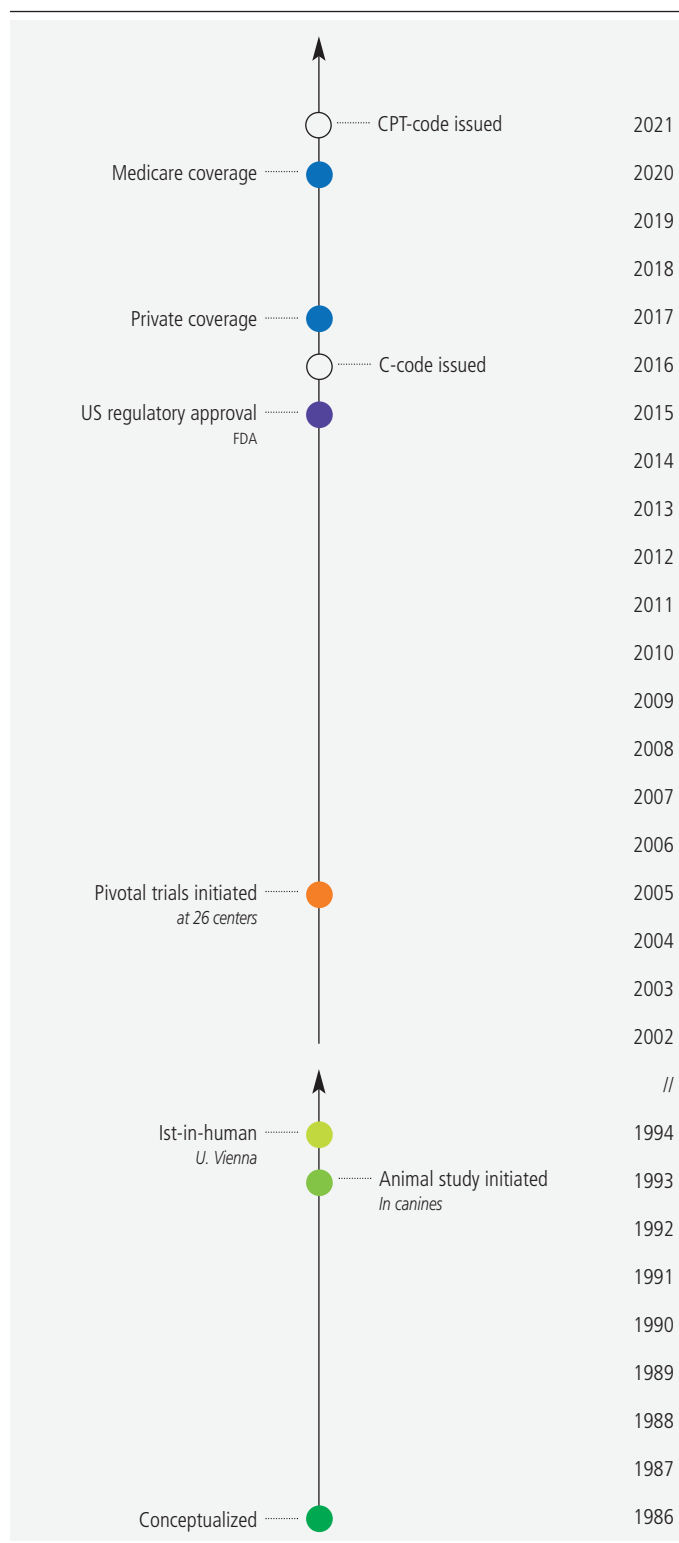
Indications



Indication Timeline Transrectal Prostate Cancer



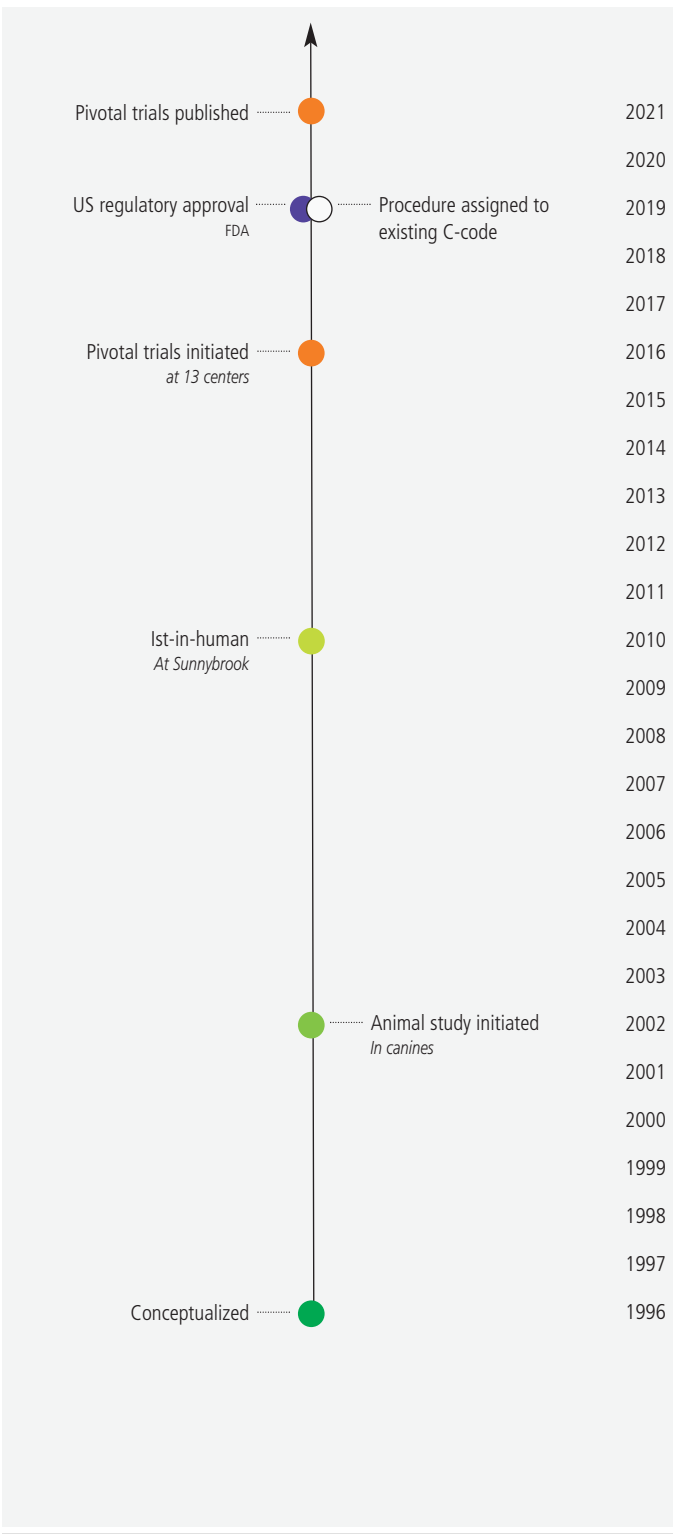
■ Conceptual ■ Preclinical ■ 1st-in-human ■ Pilot trials ■ Pivotal trials ■ FDA approval ■ US reimbursement



Indication Timeline
Transurethral Prostate Cancer



■ Conceptual ■ Preclinical ■ 1st-in-human ■ Pilot trials ■ Pivotal trials ■ FDA approval ■ US reimbursement



Indication Timeline
Uterine Fibroids



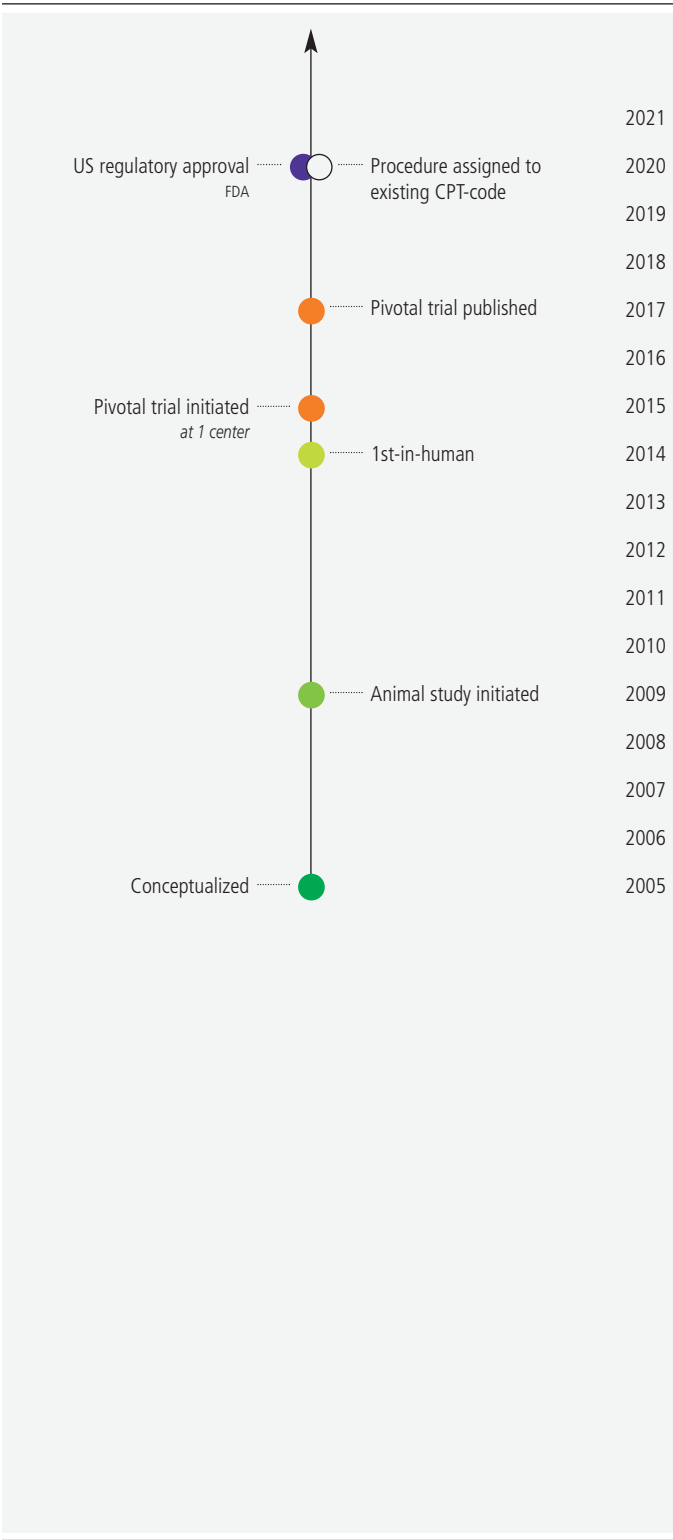
■ Conceptual ■ Preclinical ■ 1st-in-human ■ Pilot trials ■ Pivotal trials ■ FDA approval ■ US reimbursement



Indication Timeline
Osteoid Osteoma



■ Conceptual ■ Preclinical ■ 1st-in-human ■ Pilot trials ■ Pivotal trials ■ FDA approval ■ US reimbursement



Indication Timeline Bone Metastases



■ Conceptual ■ Preclinical ■ 1st-in-human ■ Pilot trials ■ Pivotal trials ■ FDA approval ■ US reimbursement



Indication Timeline Essential Tremor



■ Conceptual
 ■ Preclinical
 ■ 1st-in-human
 ■ Pilot trials
 ■ Pivotal trials
 ■ FDA approval
 ■ US reimbursement

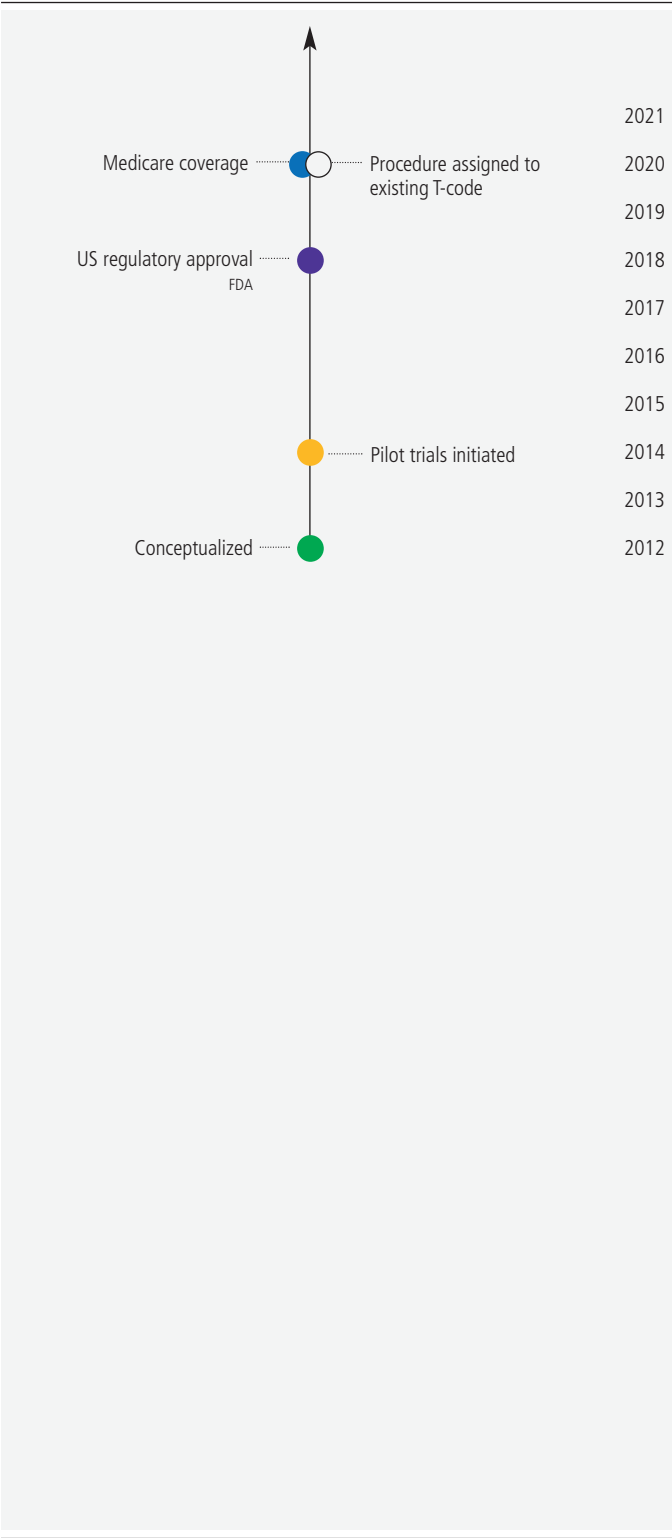


Indication Timeline

Parkinson's Tremor



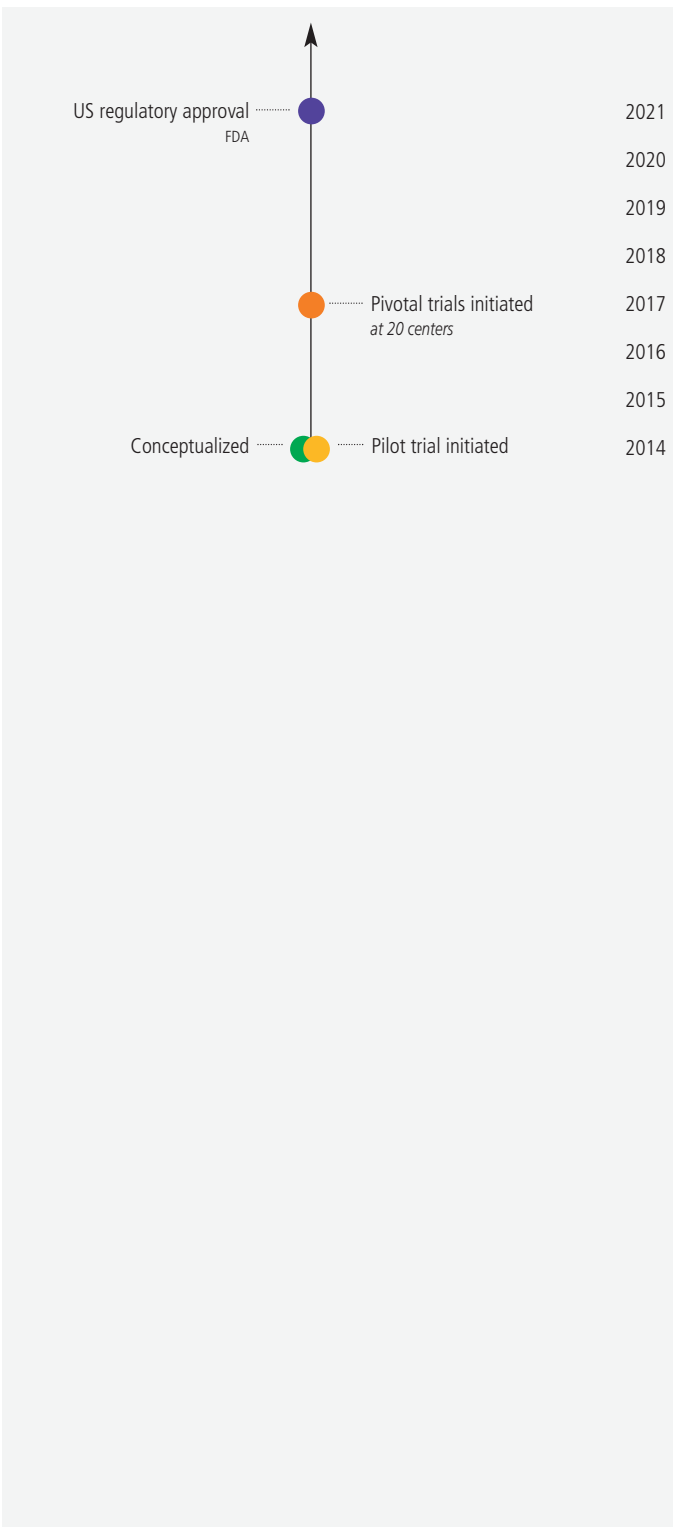
■ Conceptual ■ Preclinical ■ 1st-in-human ■ Pilot trials ■ Pivotal trials ■ FDA approval ■ US reimbursement



Indication Timeline
Parkinson's Dyskinesia



■ Conceptual ■ Preclinical ■ 1st-in-human ■ Pilot trials ■ Pivotal trials ■ FDA approval ■ US reimbursement



2022 State of the Field

This case study appears in the *2022 State of the Field Report* which is available on the Foundation's website.

The report documents the progress that is only possible through the hard work, time, and resources of everyone in our community.

