REGENERATIVE medicine
44 medical centers

$6.1 billion in annual revenue

482 clinics

269 senior living centers

190,000 Sanford Health Plan members

1,453 physicians, 1,001 advanced practice providers and 8,179 registered nurses delivering care in more than 80 specialty areas

49,086 employees

Sanford Health annual statistics:

- 5.4 million outpatient and clinic visits
- 86,305 admissions
- 138,881 surgeries and procedures
- 9,436 births
- 212,332 emergency department visits
- 2.8 million post-acute/skilled census
- 687,228 assisted living census
- 1.3 million senior living census
Integrated Approach

**DISCOVERY**
How does it work?

**APPLICATION**
How well does it work in real world settings?

**TRANSLATIONAL**
Does it apply to the human condition?

**CLINICAL**
What effect does it have in patients?

- **FIRST** type 1 diabetes trial to receive FDA fast-track status
- **FIRST** site to open and enroll a patient on a HER2 vaccine trial
- **FIRST** FDA-approved clinical trial for use of stem cells in partial rotator cuff tears
- Part of **FIRST** successful gene therapy trial for CLN6—Batten disease
SANFORD’S REGENERATIVE MEDICINE TRIALS
WRIST OSTEOARTHRITIS

Safety and efficacy of Adipose-Derived Stem Cells (ADSCs)

Prospective, randomized, double-blinded, active-controlled

40 subjects: 20 treatment and 20 control

All subjects undergo liposuction

Follow-ups include
  • Physician visits
  • Patient Reported Outcomes
  • MRI
Safety and efficacy of ADSCs

- Safety: % of Treatment-Related Adverse Events
- Efficacy: VAS Pain, Oswestry Disability Index (ODI), Global Pain Scale, MRI

Prospective, randomized, active-controlled

40 subjects: 20 treatment and 20 control

Only treatment subjects undergo a liposuction

Eligibility includes diagnosis of moderate facet joint syndrome, MRI, diagnostic facet injection and physical examination

Up to four facet joints can be selected for treatment per the investigator
**PARTIAL THICKNESS ROTATOR CUFF TEAR**

**Pivotal Study**
Prospective, double-blinded, active-controlled

246 subjects: 2:1 Randomization

All subjects undergo liposuction

Ultrasound-guided injections

Follow up includes:
- Physician visits
- Patient Reported Outcomes
- MRI
Multicenter trial of stem cell therapy for osteoarthritis (MILES) Study

Partnership with Sanford Health, Emory University, Duke University and the Andrews Research Education Foundation

Prospective, single blinded randomized controlled safety and efficacy comparing MSCs of various sources

480 subjects - 120 collectively in Fargo and Sioux Falls

Four treatment options:
- Bone marrow concentration
- ADSCs
- Stem cells from Umbilical Cord Tissue
- Corticosteroid injection