

WOUND HEALING EXPERIENCE AS OF 2016

WOUND HEALING SERVICES

- Gap analysis and clinical development plan
- IND submissions
- Protocol, IB, ICF, CRF
- Data Management & Statistics
- Site finding and management
- Recruitment and enrollment
- Online randomization, stratification
- Clinical Monitoring
- Safety Monitoring and SAE database
- Multi-study Integrated Safety Database
- ISS / ISE
- PMA submission – FDA Advisory Committee
- NDA, BLA, PMA

WOUND HEALING EXPERIENCE

- Burns
- Diabetic foot ulcer
- Pressure wounds
- Skin graft wound (split skin)
- Surgical wound
- Venous leg ulcer
- Biologic substance (proteins, cells & RNA)
- Combination – Device Biologic
- Skin matrices & dressings
 - Related:
 - Antiseptic
 - Gel (barrier and anti-infective)
 - 505 (b)(2) products

Clinical Trials	# Studies	# Sites	# Patients
Phase I	14	36	406
Phase II	13	123	1,301
Phase III	11	421	4,555
Phase IV	10	85	6,545
	48	665	13,007

BIOLOGICS

- Anti-Infective
- Burns
- DFU
- Fibrin Mesh
- Fibrin Spray
- VLU

DEVICES

- Adhesions
- Burns
- DFU
- Tissue Repair
- Pressure Ulcers
- VLU

DRUGS

- Adhesions
- Burns
- DFU
- Tissue Repair
- Pressure Ulcers
- VLU

Where **Experience** is the Difference