

# Teamwork in the Development of Orthobiologic Materials

MMA Physician Leadership Effectiveness Program

Bozeman, MT 11/21/14

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# Disclaimers

Michael Mansfield MS, CTBS

Michael Mansfield is a salaried employee of Bacterin International and holds stock options in the company.

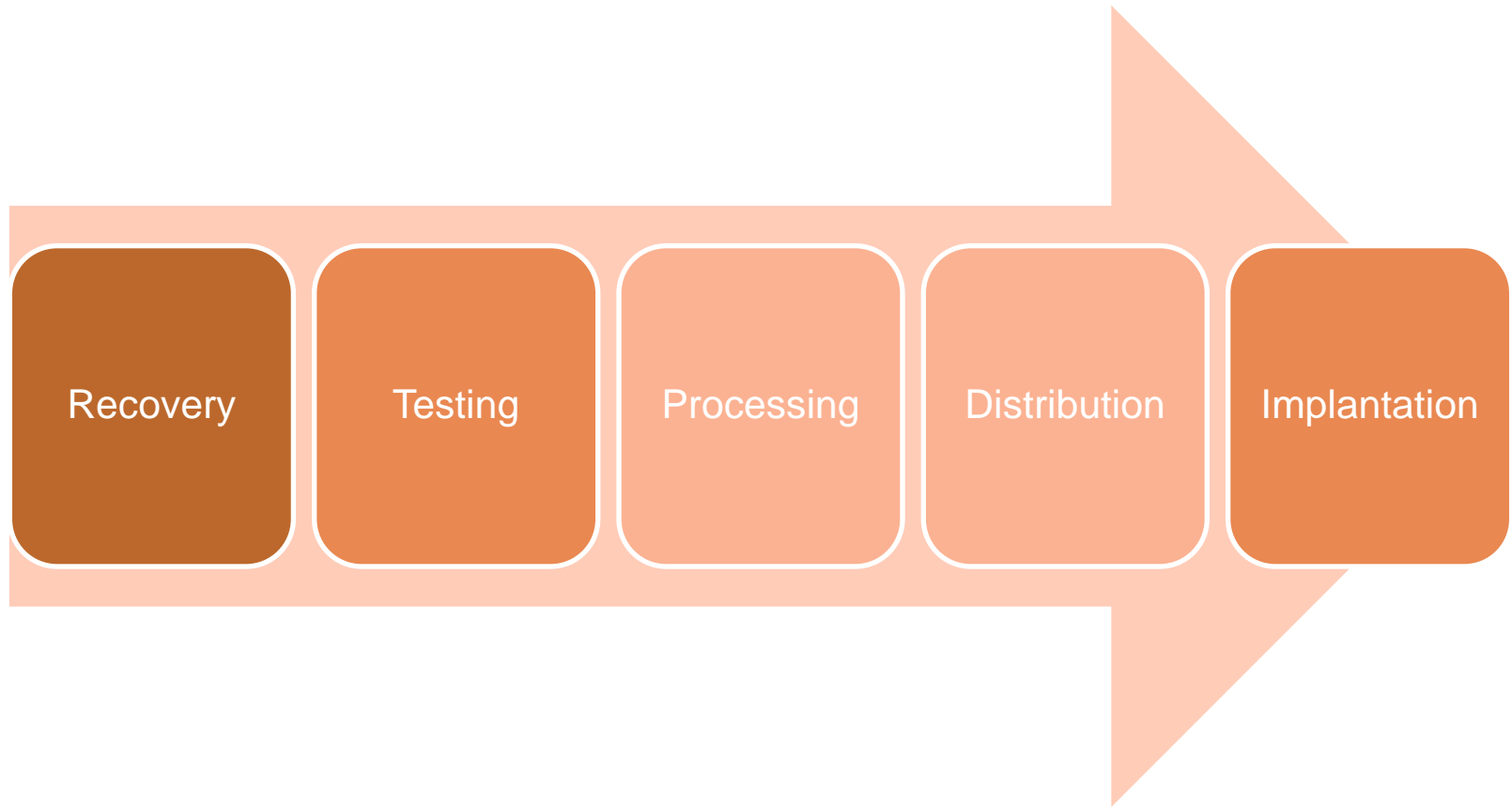


## **Bacterin is a Montana Tissue Bank founded in 2005**

Processor and distributor of allograft tissue and medical devices for transplant. Bacterin is the 4th largest distributor of Demineralized Bone Matrix (DBM) in the United States

# The Gift of Donation

Teamwork from Recovery to Implantation



# Development Pathways

The Twin Juggernauts of the FDA

## Allograft Materials

- Minimally manipulated tissue
- Intended for homologous use only
- Regulated by CBER
  - 21 CFR Part 1271
  - Section 361 PHSA

## Medical Devices

- Multiple classes based on perceived potential harm
- Specific indications based submitted clinical/preclinical work
- Regulated by CDRH
  - 21 CFR Part 800 and others

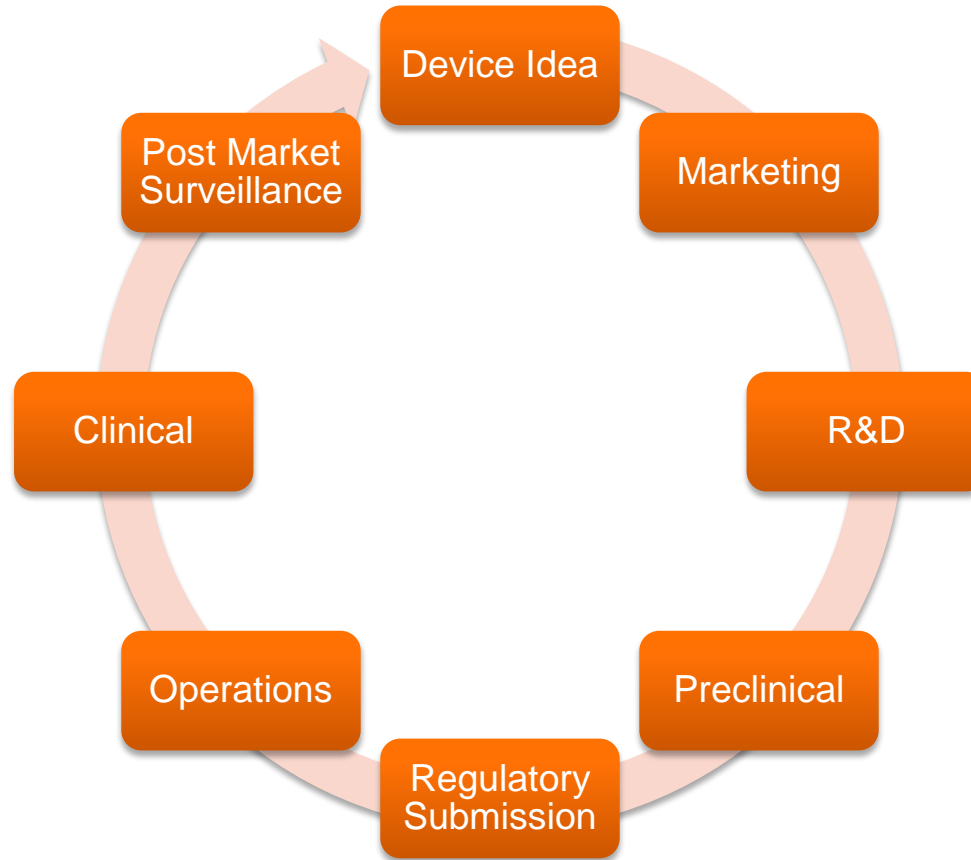
# Allograft Implant Development

Streamlined development path



# Device Implant Development

More stringent regulatory controls



# Clinically Demonstrated Efficacy

## Collaboration with Clinicians

- Bleazey and Brigido (2012) Reconstruction of complex osteochondral lesions of the talus with cylindrical sponge allograft and particulate juvenile cartilage graft: Provisional results with a short term follow-up. *Foot & Ankle Specialist*. Oct; 5(5):300-305
- Brigido et al (2013) A retrospective analysis evaluating allogeneic cancellous bone sponge for foot and ankle arthrodesis. *The Journal of Foot & Ankle Surgery*. 52: 28-21.
- Girasole et al (2013) Transforaminal lumbar interbody fusion rates in patients using a novel titanium implant and demineralized cancellous allograft bone sponge. *The International Journal of Spine Surgery*. 7: e95-e100.
- Schallenberger et al. Comparison of the Osteogenic Potential of OsteoSelect DBM Putty to NovaBone Calcium-Phosphosilicate Synthetic Putty in a Cranial Defect Model. *Journal of Craniofacial Surgery*.
- Kiely et al. Evaluation of a new formulation of demineralized bone matrix putty in a rabbit posterolateral spinal fusion model. *The Spine Journal*.



# Clinically Demonstrated Efficacy

## Collaborations with Clinicians

- Brigido et al. Prospective, 25+ patient evaluation of OsteoSponge for F&A fusion. *Orthopedics*.
- Brigido et al. Clinical series hMatrix + Aliqua silver dressing for treatment of wounds. *Orthopedic Wound Journal*. In press.
- Brigido et al. Retrospective clinical series of OsteoSponge SC for talar dome reconstruction with 2+ year follow up. *Foot & Ankle Specialist*. In press.
- Brigido et al. Retrospective clinical series of OsteoSponge SC and DeNovo for talar dome reconstruction with 1 year follow up. *Foot & Ankle Specialist*. Accepted pending revisions.

# Researching Innovation in Montana

Montana Board of Research and Commercialization Technology

- Acellular Nerve Allografts for Transplantation (2014)
  - Mark Schallenberger, MS Principle Investigator
  - Collaboration with the Mayo Clinic
- Allograft Based Bone Void Filler (2007)
  - Greg Juda, PhD Principle Investigator
  - Successfully commercialized 2010





 **BACTERIN**  
Thank You