Bone Marrow Aspirate Concentrate (BMAC): The Next 5 Years

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Mission: Translate orthobiologic therapy into routine clinical practice of orthopedics and sports medicine in a safe, scientifically validated, efficient, streamlined, and FDA approved manner.

Current Barriers:

1. Lack of evidence
2. Lack of insurance coverage
3. Rent-A-Machine sales model
4. Expensive disposable manufacturing kits
5. Lack of prcedureal knowhow and standardization
6. Unknown Purity, Potency, Identity (FDA CMC)
7. Not scalable to 30 million Americans with osteoarthritis

BMAC – Is it a procedure or is it a drug? (or both?)

FDA Pathway for Biologic Drug approval process: Investigational New Drug

Orthopedic Moonshot – BMAC IND – Multicenter Phase II Trial

- Industry Sponsorship
- Transfer sponsorship of existing IND to professional society representatives

Coordinate with Biorepository (BARB) and Registry Committees

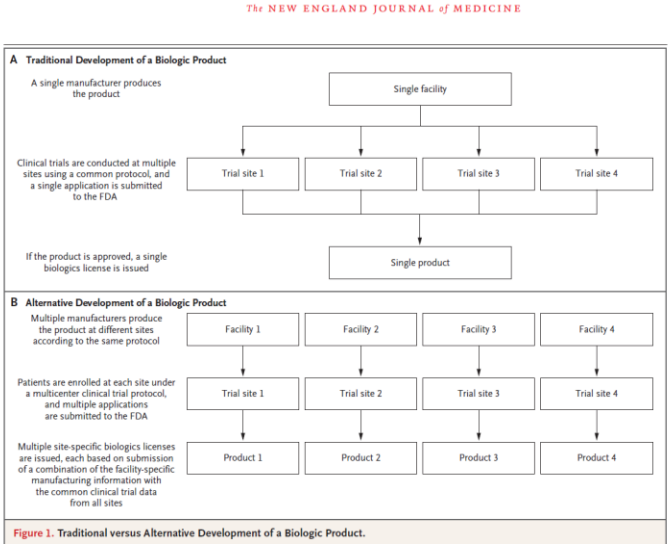

Figure 1. Traditional versus Alternative Development of a Biologic Product.

From Marks and Gottlieb, NEJM 2018

FDA Advocacy - novel "Minimally Manufactured" Autologous Product Status

not cGMP and not "not cGMP"