



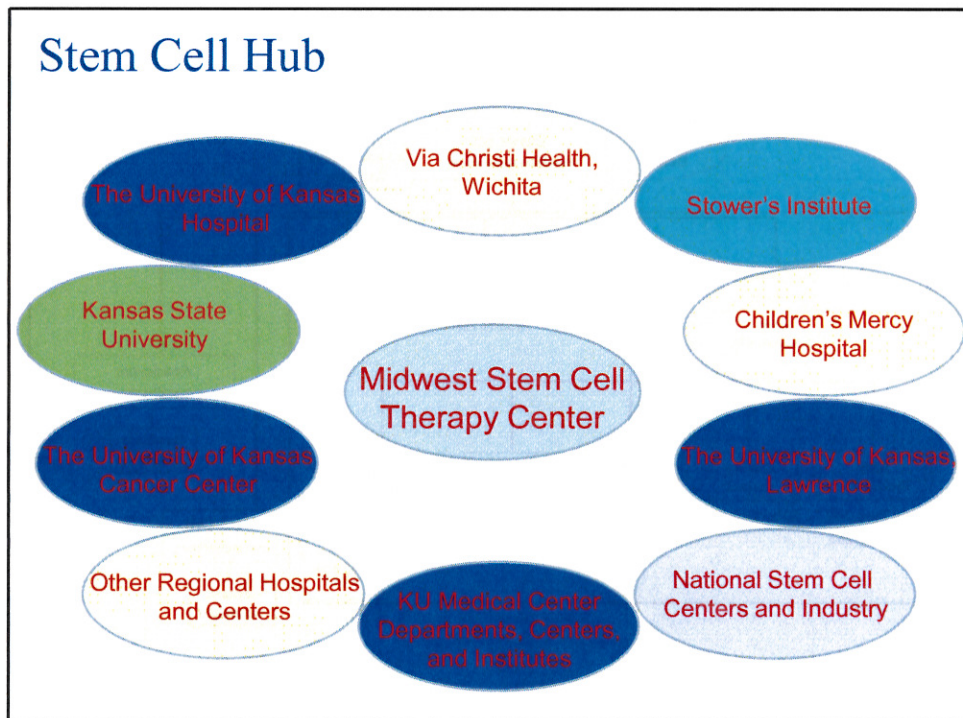
Midwest Stem Cell Therapy Center

Status Update
April 30, 2015

Buddhadeb Dawn, M.D.
Director, Midwest Stem Cell Therapy Center

Maureen and Marvin Dunn Professor
Director, Division of Cardiovascular Diseases
Director, Cardiovascular Research Institute
Vice Chairman for Research, Department of Medicine

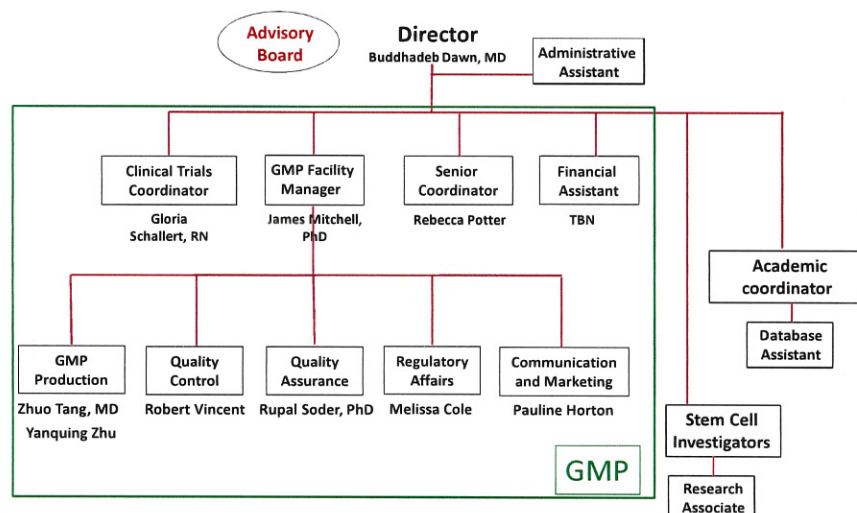




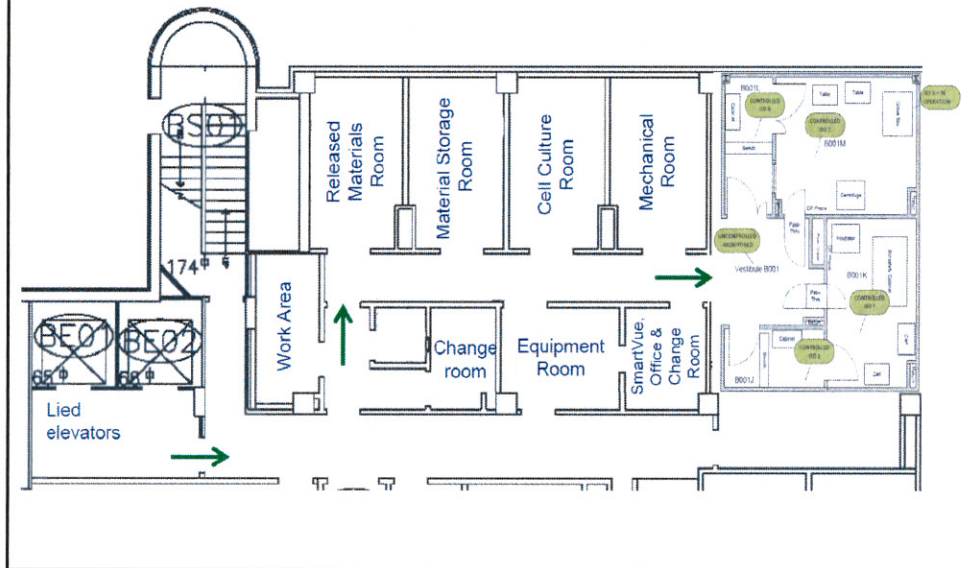
Objectives of the Center - I

- To **advance** adult, cord blood and related stem cell research and therapies for **patient treatment**
- To serve as a **core facility** to produce clinical grade stem cells
- To initiate **clinical trials** with adult, cord blood, and related stem cells

MSCTC Organizational Chart



GMP Facility – Lied Building



Key FDA Related Items

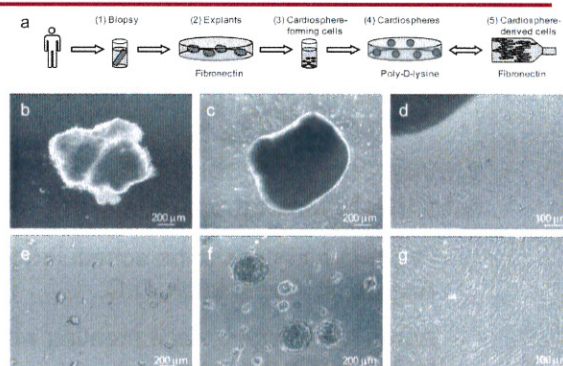
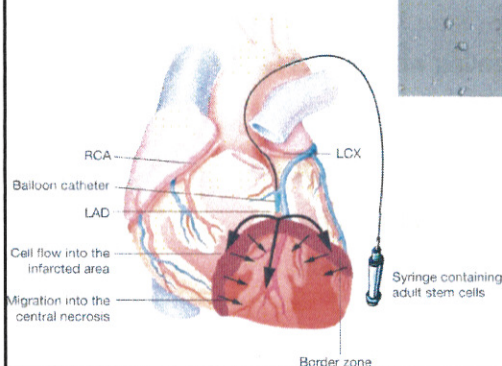
- GMP facility is now registered with the FDA
- Developed FDA contacts in both Washington, D.C. and the FDA District Office in Lenexa, KS
 - Pre-IND meetings to be scheduled for GvHD and Aplastic Anemia in Washington, D.C.
 - Agreed to a face-to-face meeting with District Office staff prior to first IND submission
- Pre-clinical submission template developed
 - Can customize for use in all pre-clinical efforts
 - Is the basis for an electronic IND submission

Focus Areas for Adult Stem Cell Therapy

- Stroke and Neurodegenerative diseases
- Cancer and immunotherapy
- Cardiac and vascular
- Musculoskeletal, trauma, skin, burn, wounds, autoimmune diseases

Current Clinical Trials

ALLSTAR:
Heart-derived
stem cells for
patients with heart
attack



PreSERVE AMI:
Bone marrow-
derived CD34+
cells for patients
with heart attack

Current Preclinical Projects

Graft vs. Host Disease (GvHD)

- Collaboration with University of Kansas Cancer Center
- Cells available for animal efficacy study
- IND template developed and details identified
- Scale-up to be initiated

Preclinical Projects

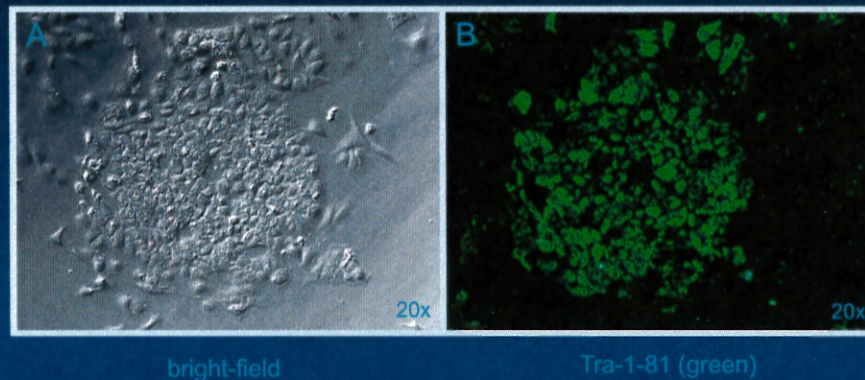
Amyotrophic Lateral Sclerosis (Lou Gehrig's Disease)

- KU Dept of Neurology collaboration
- Cells and media provided for initial Proof of Concept

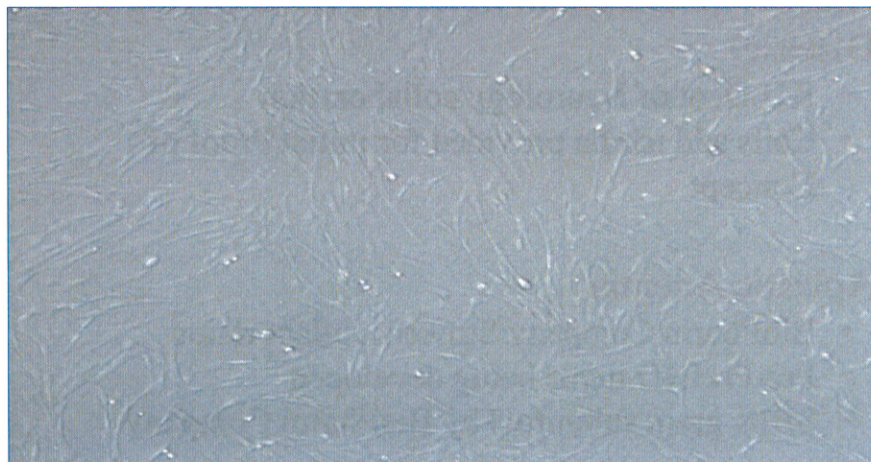
Aplastic Anemia

- BioPharm Company/Stowers collaboration
- Pre-PreIND items being developed
- SBIR grant submitted by BioPharm Company

Identification of Human iPS Cells by Live Staining with Tra-1-81 Antibody

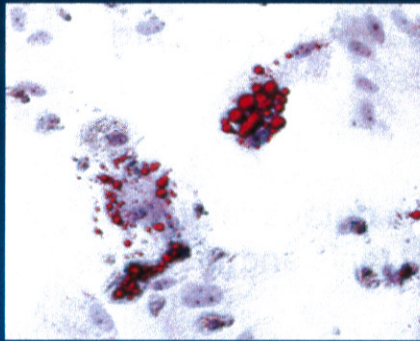


Umbilical Cord-derived Mesenchymal Stem Cells (UC-MSCs)



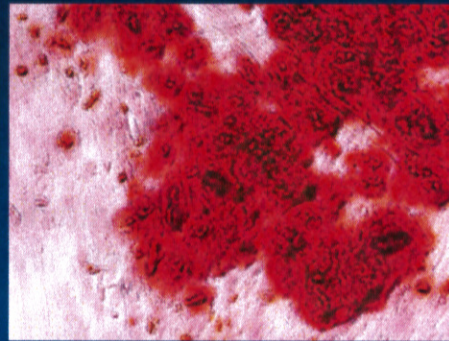
Differentiation of UC-MSCs

Differentiation into fat cells



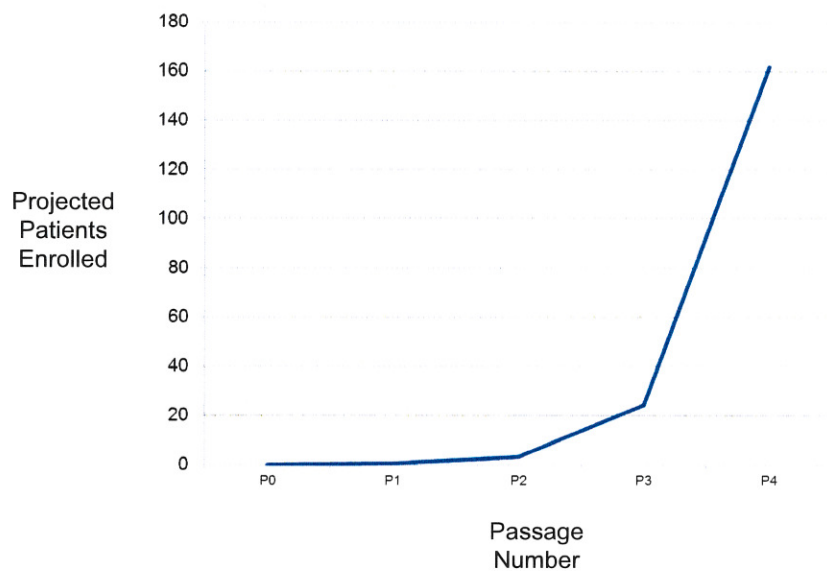
Oil red O staining showing intracellular fat vesicles

Differentiation into bone tissue



Alizarin red staining showing extracellular calcium

Projected Patients Enrolled



Objectives of the Center - II

- Informing the public on available adult, cord blood, and related stem cell therapeutic options
- Creating and maintaining a database of available stem cell clinical trials and therapies
- Foster a regional network of physicians trained in adult stem cell therapy

Dissemination of Information

- Website (www.kumc.edu/msctc)
- Compilation of an extensive resource for adult stem cell information
- Dedicated personnel support
- Providing answers via emails/meetings
- Conferences



Funding

- FY14 – budgeted amount \$1,154,500
- FY15 – budgeted amount \$754,500
- FY16 – budgeted amount \$735,238
- FY15 operational revenues: \$29,416
- FY15 Philanthropic donations: approx. \$52,000
- Federal grant funding in the future

Major Support from KUMC

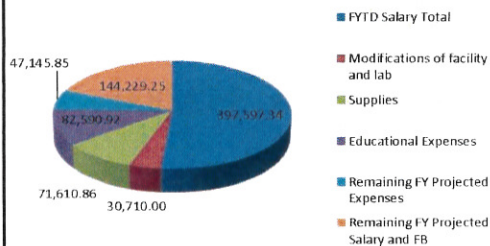
- Funds toward initial GMP construction, personnel salary and benefits
- Space and other key infrastructure support
- Administrative support
- Research Institute
- Abundance of collaborators
- Brand recognition for marketing

Expense report

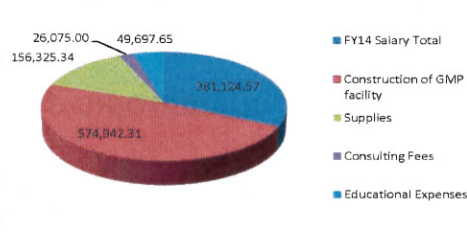
Fiscal Year Comparisons

FY15 actual expenses thru 3/30/15			FY14 Final Expenses		
<i>FYTD Salary Total</i>	<i>397,597.34</i>	<i>51%</i>	<i>FY14 Salary Total</i>	<i>381,124.57</i>	<i>32%</i>
<i>Modifications of facility and lab</i>	<i>30,710.00</i>	<i>4%</i>	<i>Construction of GMP facility</i>	<i>574,942.31</i>	<i>48%</i>
<i>Supplies</i>	<i>71,610.86</i>	<i>9%</i>	<i>Supplies</i>	<i>156,325.34</i>	<i>13%</i>
<i>Consulting fees</i>	<i>0.00</i>	<i>0%</i>	<i>Consulting Fees</i>	<i>26,075.00</i>	<i>2%</i>
<i>Educational Expenses</i>	<i>82,590.92</i>	<i>11%</i>	<i>Educational Expenses</i>	<i>49,697.65</i>	<i>4%</i>
<i>Remaining FY Projected Expenses</i>	<i>47,145.85</i>	<i>33%</i>			
<i>Remaining FY Projected Salary and FB</i>	<i>144,229.25</i>	<i>19%</i>			
	<u>773,884.22</u>			<u>1,188,164.87</u>	

Midwest Stem Cell Therapy Center Summary of expenses
FY15 expenses through 3/30/15



Midwest Stem Cell Therapy Center Summary of FINAL expenses
FY14



MSCTC Vision for Growth

- Advance cutting-edge adult stem cell therapy
 - multi-center trials
 - Recruit eminent investigators
 - Expand MSCTC clinical trial workforce
- Producing patient-specific adult stem cells locally and also generating new business
 - by expanding the GMP facility
- Enable cellular engineering and innovation
 - state-of-the-art instrumentation and technique
- Advance basic stem cell research
 - Recruit excellent basic stem cell scientists

THANK YOU