

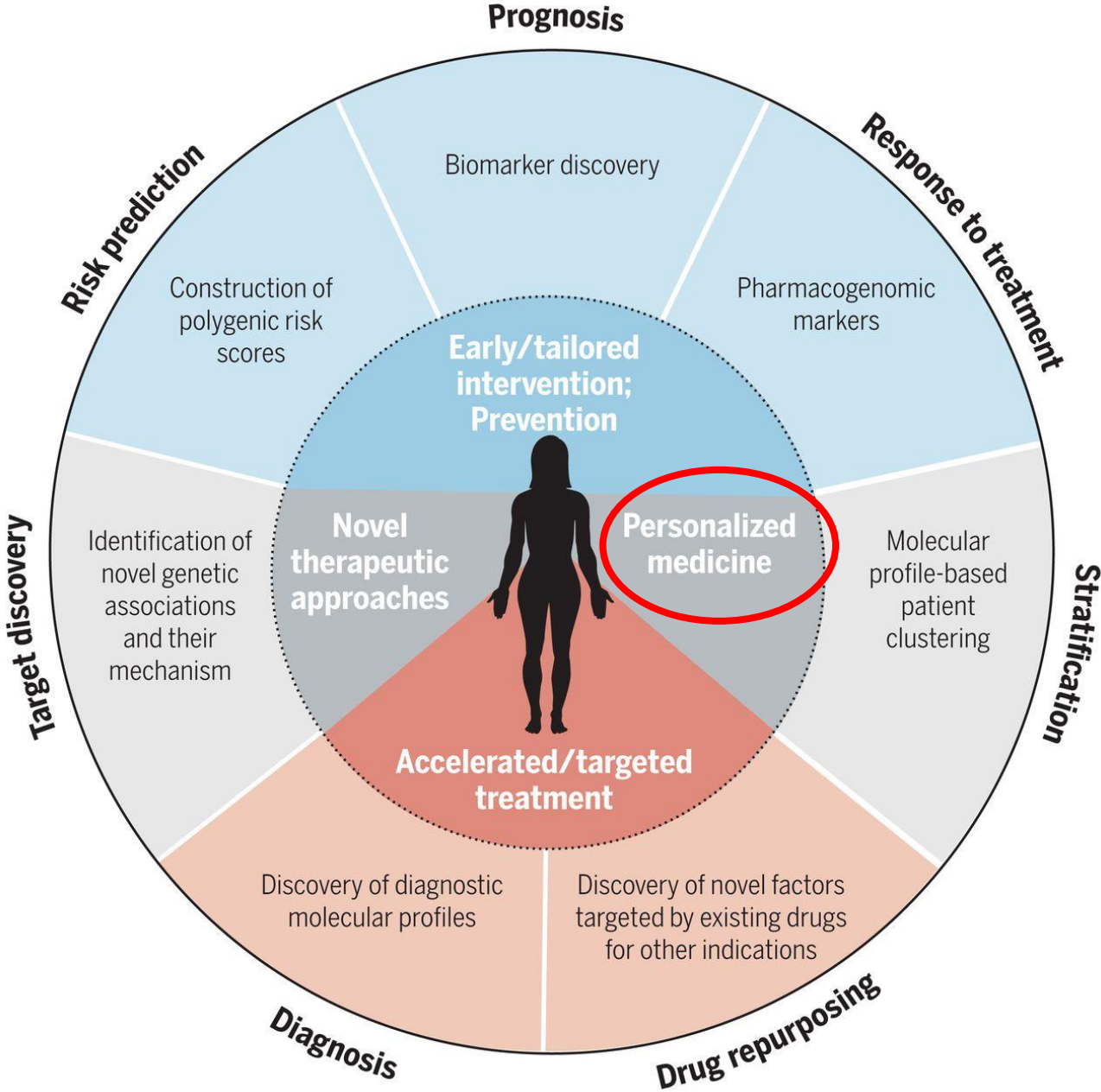


Personalised medicine research infrastructure at the University of Szeged - Bench to Bedside: Translating Science from the Lab to the Clinic

Zoltán Veréb

Personalized Medicine Research Infrastructure, University of Szeged, Szeged

TRANSLATIONAL MEDICINE

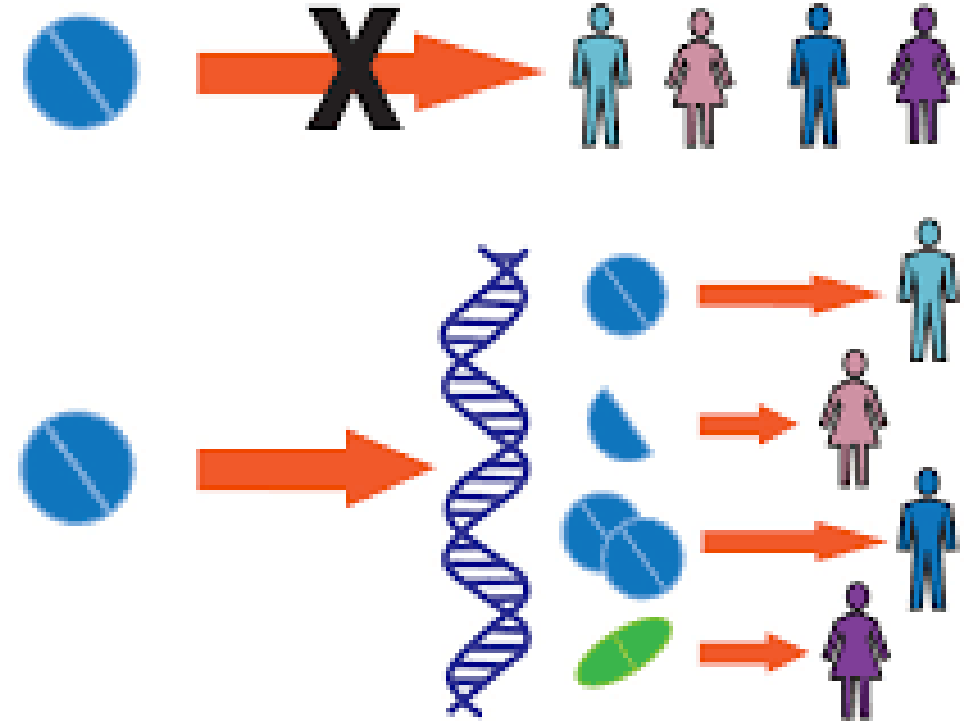


PERSONALIZED MEDICINE

OBJECTIVES

- Faster, more efficient care
- More economical care
- Patient-specific considerations taken into account
- Reduced time to treatment and recovery
- More effective therapeutic treatment

- More efficient use of materials and human resources
- Faster drug development



REGENERATIVE MEDICINE



Artificial creation of cells and tissues to repair or replace damaged or malfunctioning tissues and organs.



**Cell therapy/gene therapy procedures
(primary cells, stem cells, iPSC)**

**Tissue engineered products,
bioscaffolds, bioprinting**

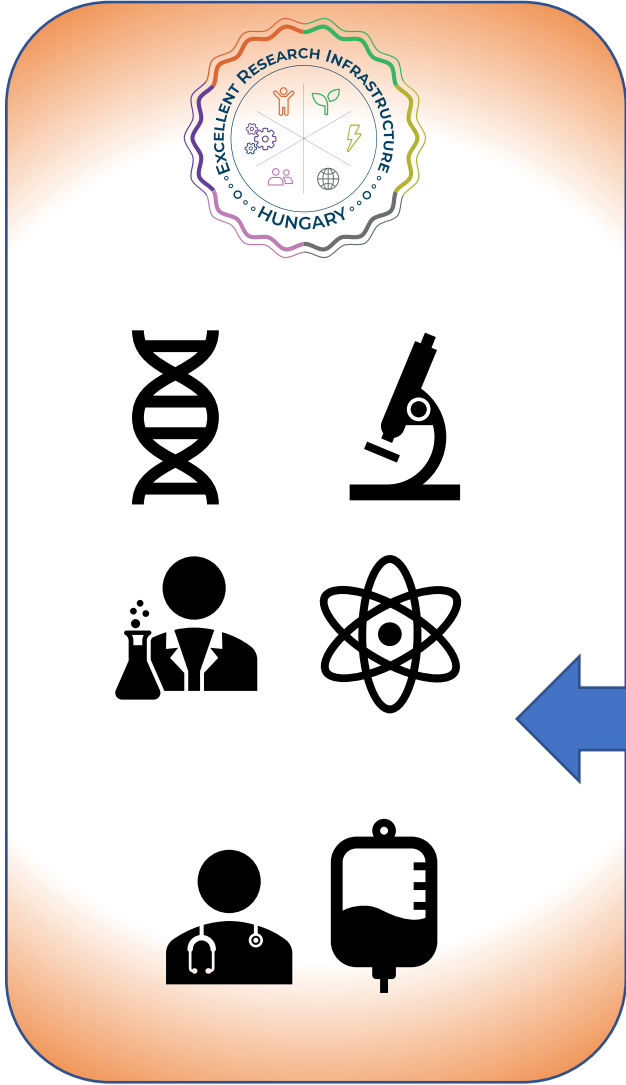
**Advanced diagnostics, Robotics,
On-a-Chip technologies, Bio-
cybernetics**

PERSONALISED MEDICINE RESEARCH INFRASTRUCTURE AT THE UNIVERSITY OF SZEGED

INFRASTRUCTURE DEVELOPMENT
SZTE BIOBANK
CELL THERAPY LABORATORY

RESEARCH AND DEVELOPMENT
KNOW HOW AND TECHNOLOGY

FOUNDINGS
GINOP-2.2.1-15-2017-00047
GINOP-2.3.3-15-2016-00040
GINOP-2.3.3-15-2016-00012



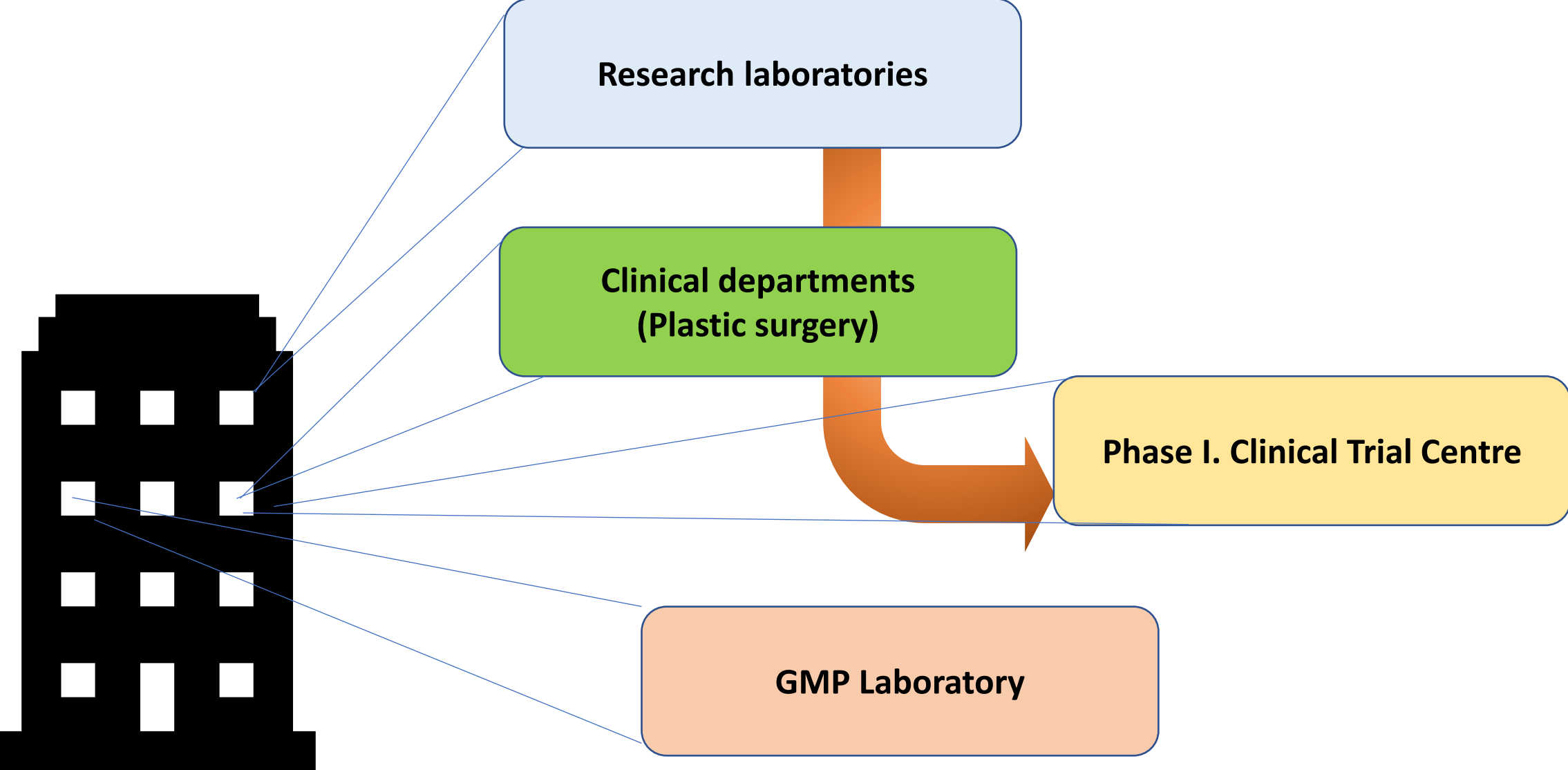
PERSONALISED MEDICINE RESEARCH INFRASTRUCTURE



RESEARCH AND DEVELOPMENT
KNOW HOW
TECHNOLOGY



PERSONALISED MEDICINE RESEARCH INFRASTRUCTURE AT THE UNIVERSITY OF SZEGED



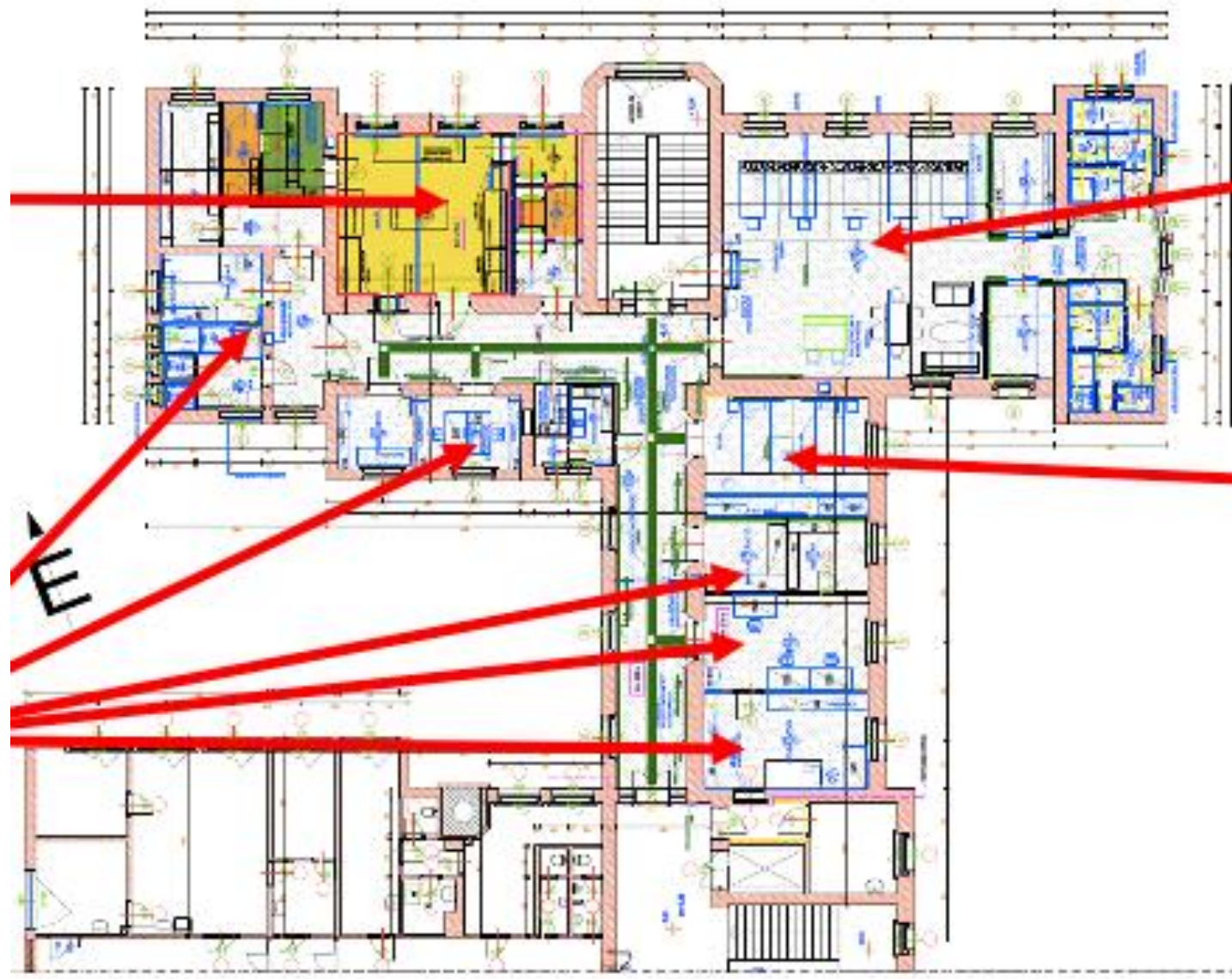
GMP LABORATORY

GMP Laboratory

Clinical beds (5)

2-bed intensive care unit

Medical examination
rooms, administration
rooms



CLINICAL PHASE I. TRIAL CENTRE



Iktatószám: OGYÉI/145-5/2021
Ügylétező: Dr. Hermann Dóra
Tárgy: minősítő határozat

Szegedi Tudományegyetem
Szent-Györgyi Albert Klinikai Központ
Bőrgyógyászati és Allergológiai Klinika
Fázis I vizsgálóhely
6720 Szeged,
Korányi fasor 6.

KRID szám: 653600102

HATÁROZAT

Az emberi felhasználásra kerülő gyógyszerekről és egyéb, a gyógyszerpiacot szabályozó törvények módosításáról szóló 2005. évi XCV. törvény (a továbbiakban: Gytv.) 3. § (2) bekezdésében, továbbá az emberi felhasználásra kerülő vizsgálati készítmények klinikai vizsgálatáról és a helyes klinikai gyakorlat alkalmazásáról szóló 35/2005 (VIII. 26.) EüM rendelet (a továbbiakban: Rendelet) 12. § (7) bekezdésében foglalt felhatalmazás alapján, az Országos Gyógyszerészeti és Élelmezés-egészségügyi Intézet (a továbbiakban: OGYÉI) előtt, 2021. január 8. napján, OGYÉI/145-1/2021 ügyszámon Szegedi Tudományegyetem Szent-Györgyi Albert Klinikai Központ, Bőrgyógyászati és Allergológiai Klinika (képviseli: Prof. Dr. Lengyel Csaba, a továbbiakban: Kérelmező) I. fázisú klinikai vizsgálatok elvégzésére alkalmas klinikai farmakológiai vizsgálóhely minősítése tárgyában, kérelemre indult minősítési eljárásban az alábbi

határozatot

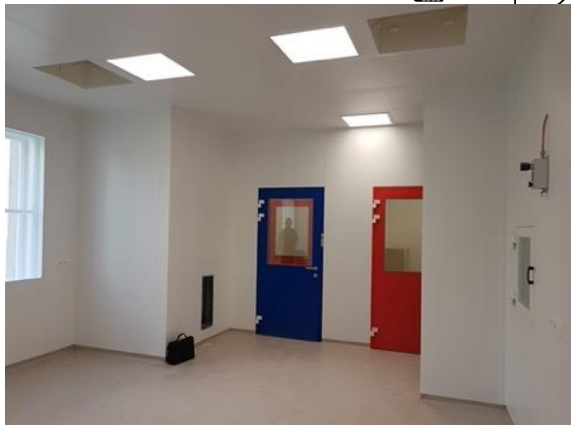
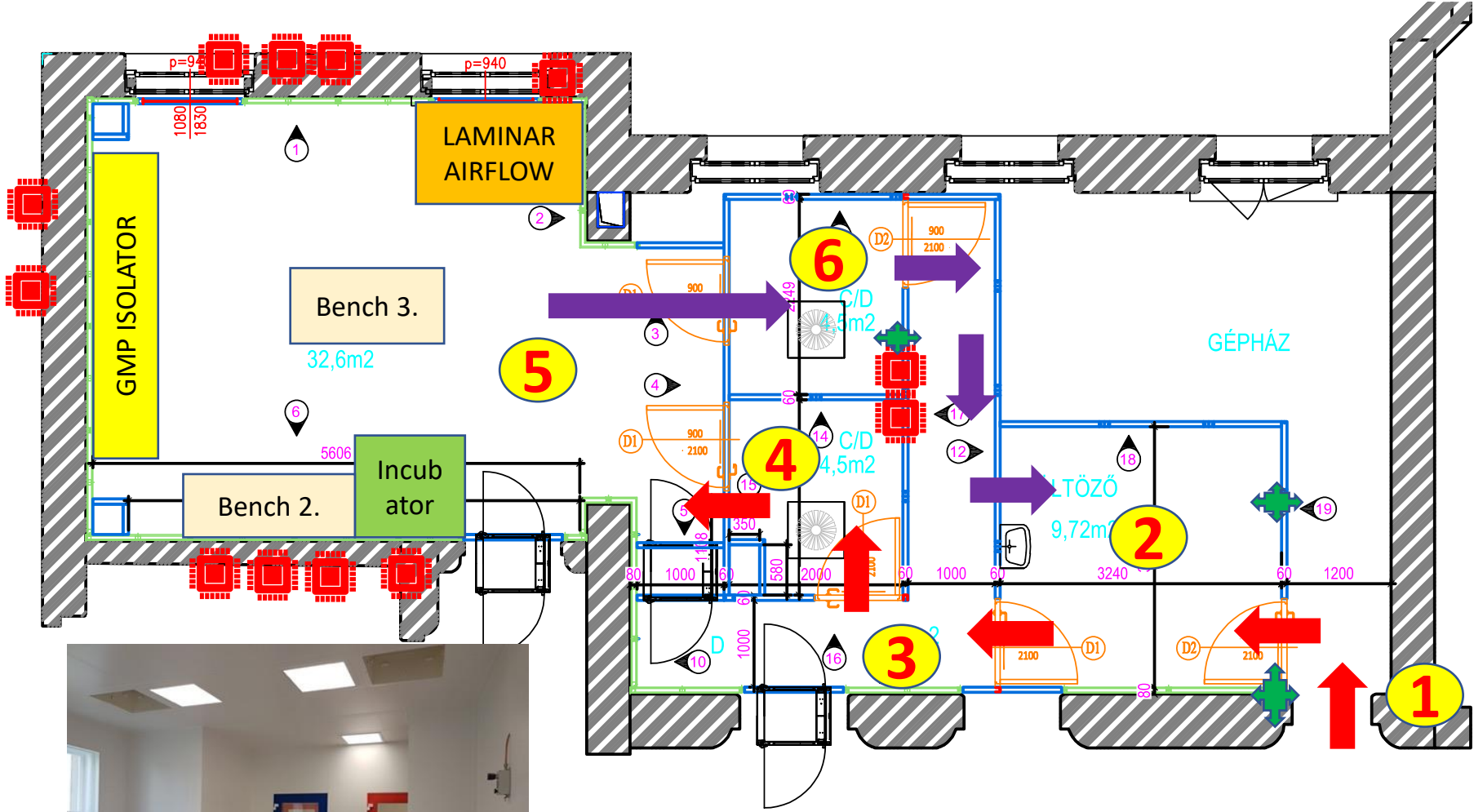
hozom.

A fenti eljárásban a Kérelmező által képviselt klinikai vizsgálóhely - az alábbiak figyelembevételével - I. fázisú klinikai vizsgálatok elvégzésére

alkalmas.

- A vizsgálóhely neve:** Szegedi Tudományegyetem Szent-Györgyi Albert Klinikai Központ Bőrgyógyászati és Allergológiai Klinika Fázis I vizsgálóhely
- A vizsgálóhely címe:** 6720 Szeged, Korányi fasor 6.
- A vizsgálóhely vezetőjének neve és beosztása:** Dr. Bende Balázs, vizsgálóhelyvezető
- A klinikai vizsgálatra szolgáló ágyszám:** 5 ágy
- A vizsgálóhely minősítésének érvényessége:** 2024. június 3.

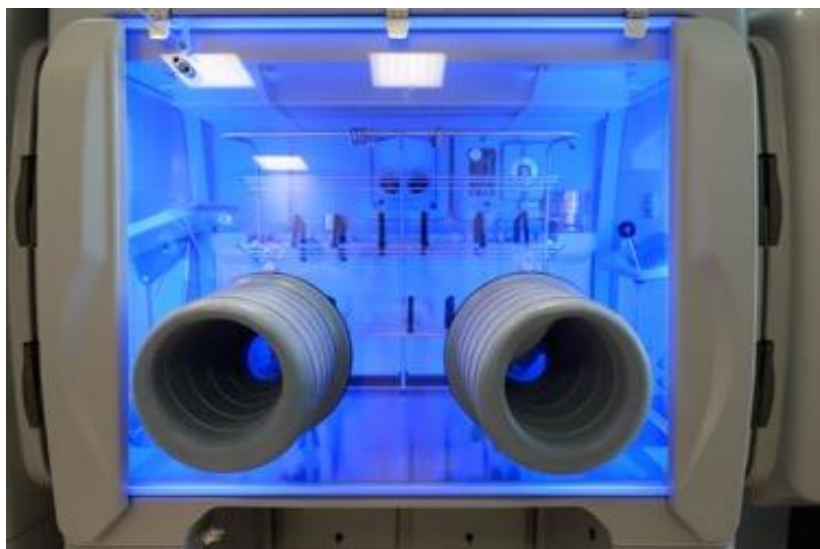
GMP LABORATORY



GMP LAB EQUIPMENTS

Modular GMP Isolator (GMP A and GMP B)
Clean room technology (GMP D and GMP C)

Cytori Celution 800 CRS



MELANOMA RESEARCH GROUP: PROTEOMIC ANALYSIS OF PROGNOSTIC AND PREDICTIVE BIOMARKERS OF MELANOMA

MM500 study

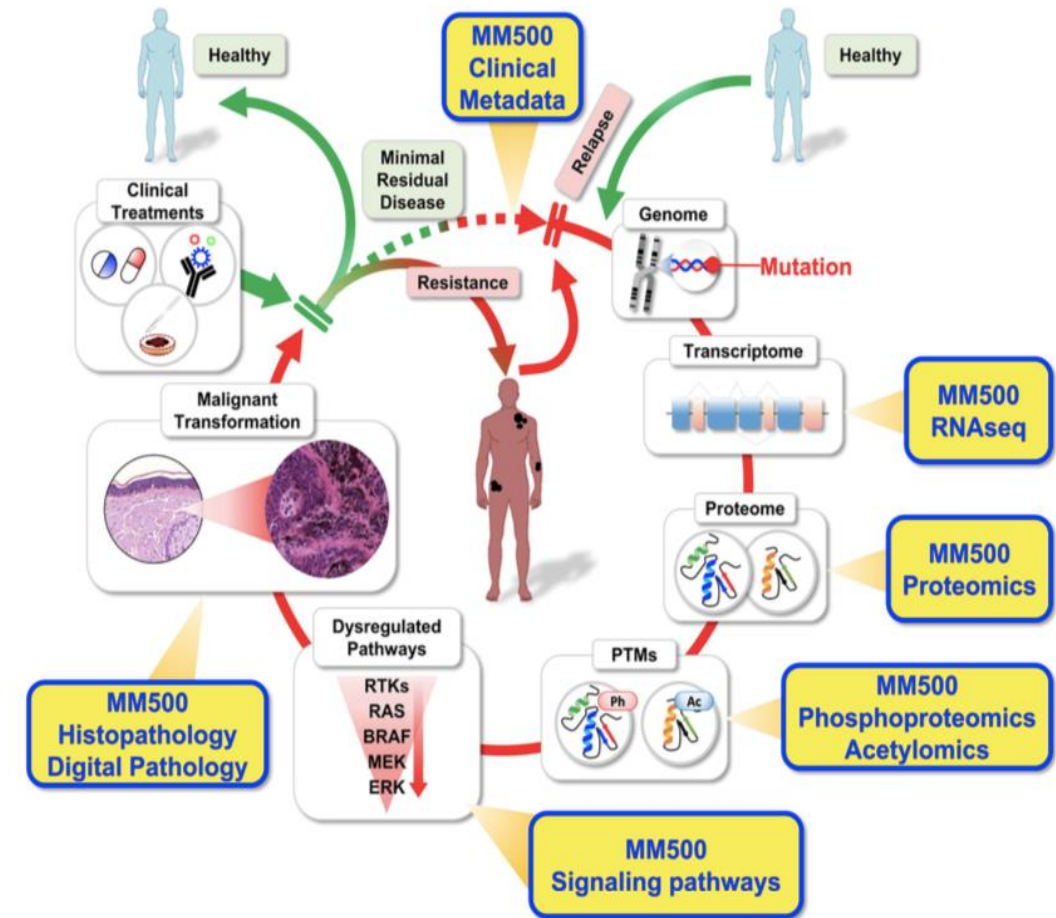
Collaborative study with the MALDI MASSPECT Proteomic Laboratory (head: Prof. Dr. György Markó-Varga) of the University of Lund.

The MM500 multicentric study was the first in the world to describe the high-resolution proteomic "fingerprint" of melanoma, which database was also added to the NIH's official repository.

Complete genomic, transcriptomic, and proteomic (OMICS) results of 500 primary and metastatic melanoma tissues and a summary of the histopathological validation of our working group.

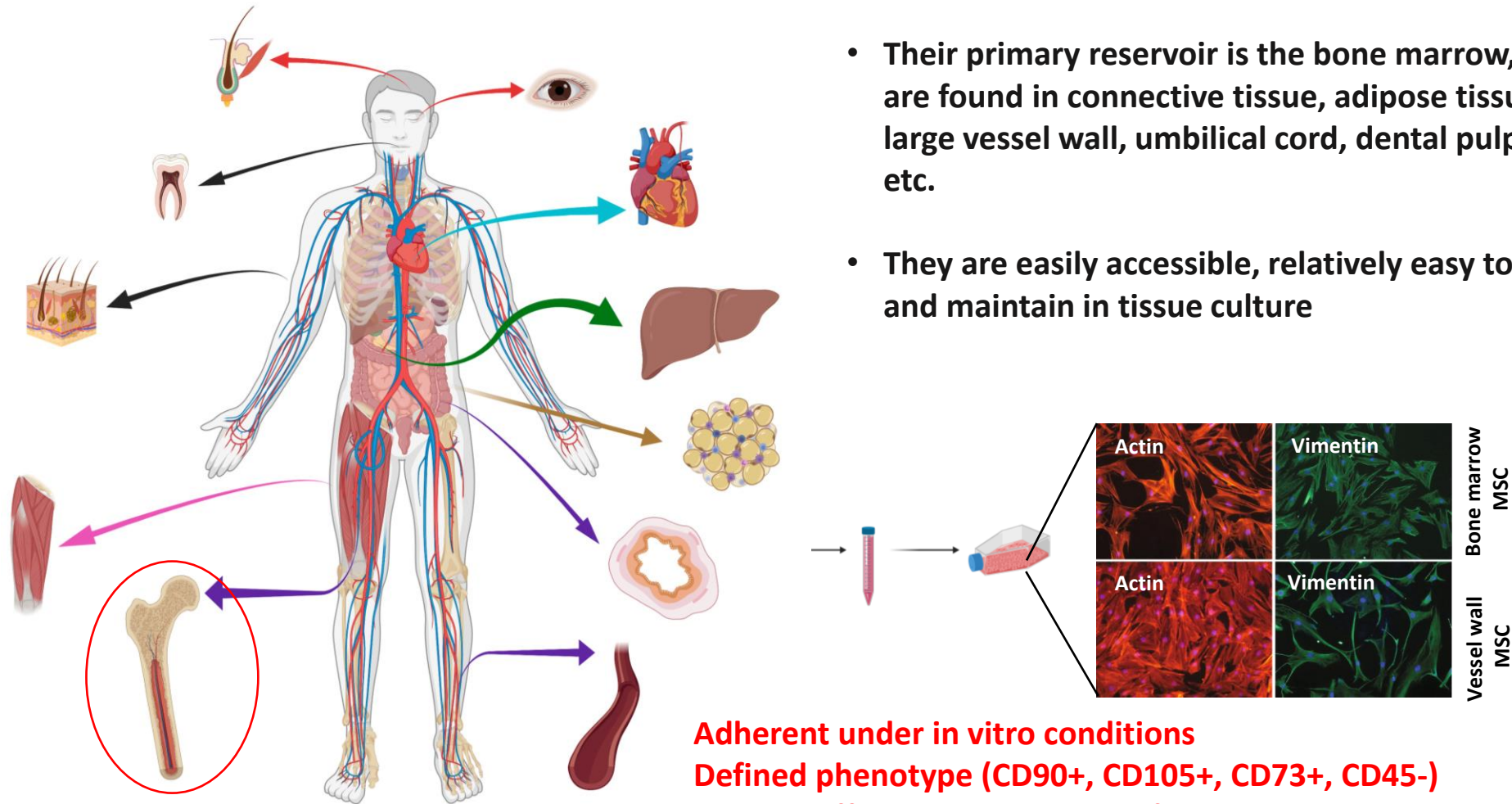
In addition to the proteomic results, with special regard to the presentation of post-translational variations and possible "driver" and therapy-associated genes.

The study covers 74% of human protein coding genes.



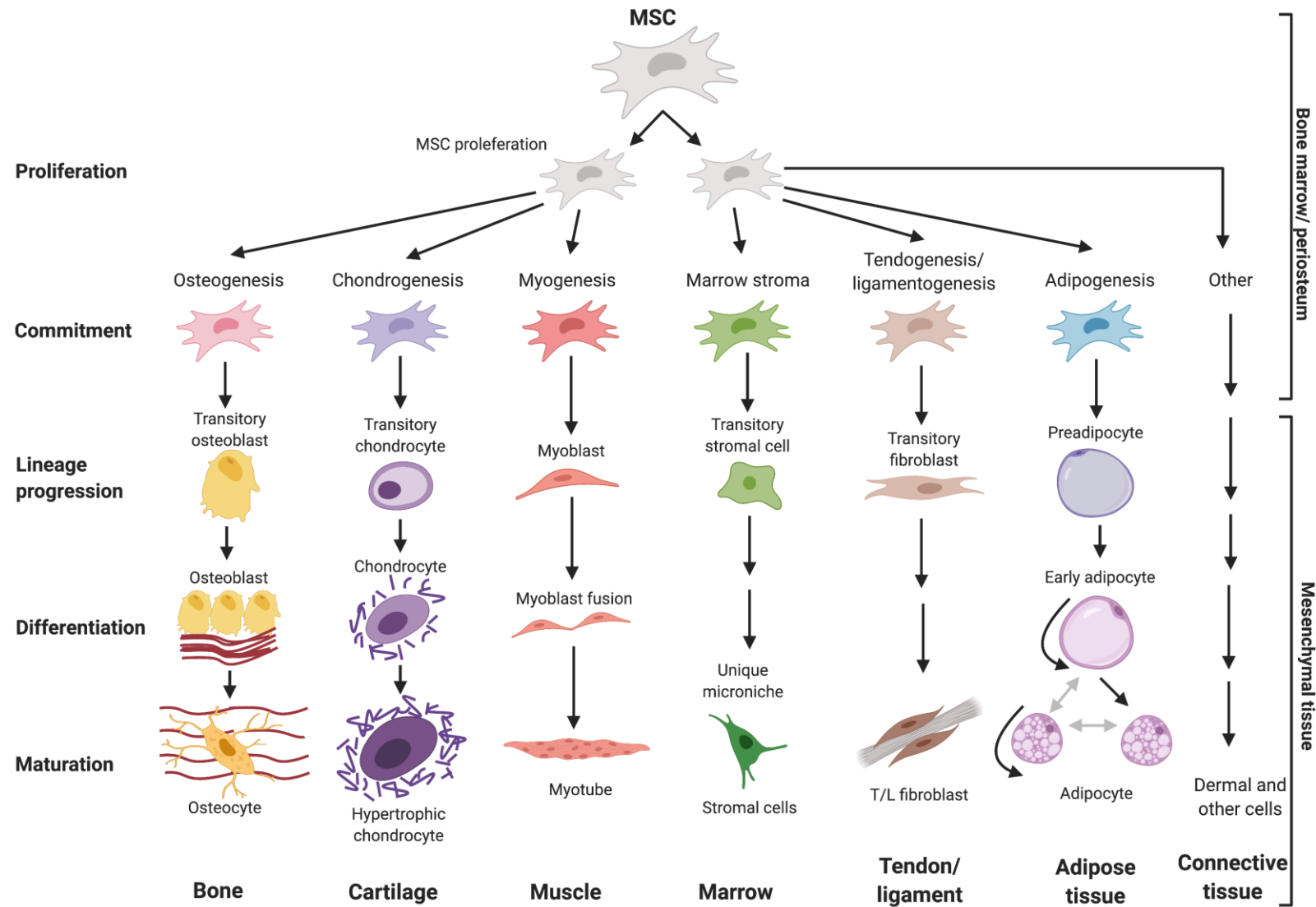
REGENERATIVE MEDICINE RESEARCH GROUP: MESENCHYMAL STEM CELLS

- Multipotent stem cells
- Their primary reservoir is the bone marrow, but they are found in connective tissue, adipose tissue, liver, large vessel wall, umbilical cord, dental pulp, cornea etc.
- They are easily accessible, relatively easy to isolate and maintain in tissue culture



Adherent under in vitro conditions
Defined phenotype (CD90+, CD105+, CD73+, CD45-)
In vitro differentiation towards fat, cartilage and bone tissue

MESENCHYMAL STEM CELLS

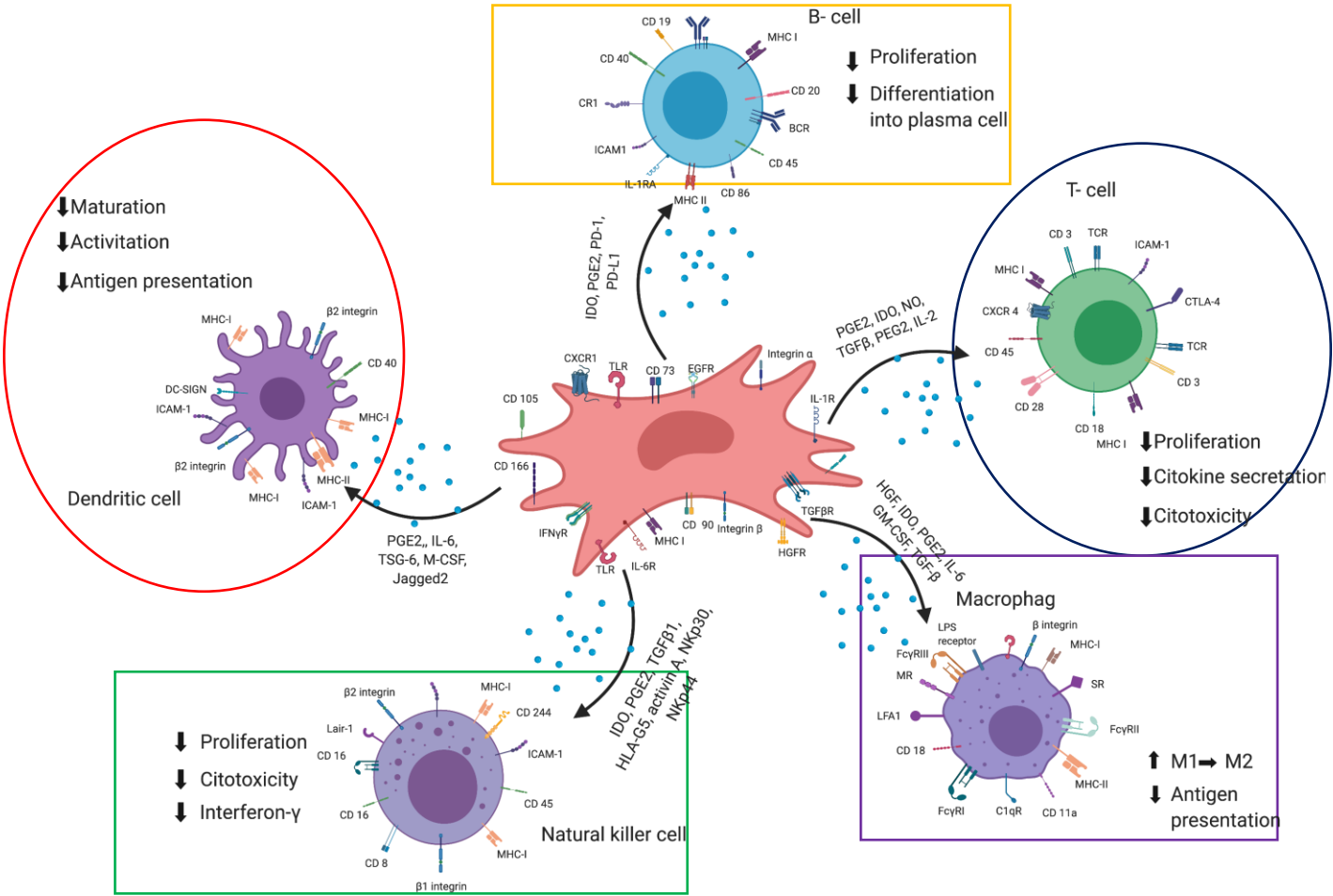


They are not immortal!
They're getting old!
They lose their potency in time!
(Inflammation, infection, ROI)

Bourin P, Bunnell BA, Casteilla L, Dominici M, Katz AJ, March KL, Redl H, Rubin JP, Yoshimura K, Gimble JM. Stromal cells from the adipose tissue-derived stromal vascular fraction and culture expanded adipose tissue-derived stromal/stem cells: A joint statement of the international federation for adipose therapeutics and science (ifats) and the international society for cellular therapy (isct). Cytotherapy 2013; 15: 641-648
Dominici M, Le Blanc K, Mueller I, Slaper-Cortenbach I, Marini F, Krause D, Deans R, Keating A, Prockop Dj, Horwitz E. Minimal criteria for defining multipotent mesenchymal stromal cells. The International Society for Cellular Therapy position statement. Cytotherapy. 2006;8(4):315-7.

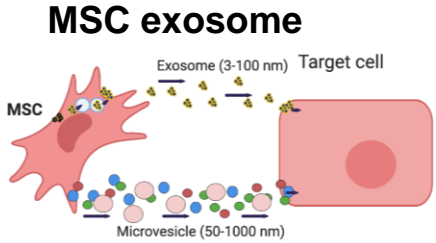
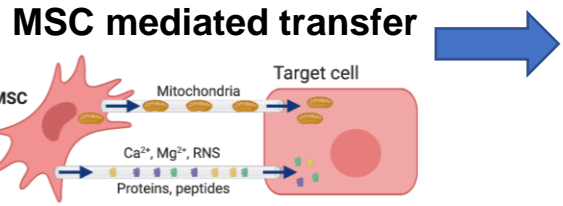
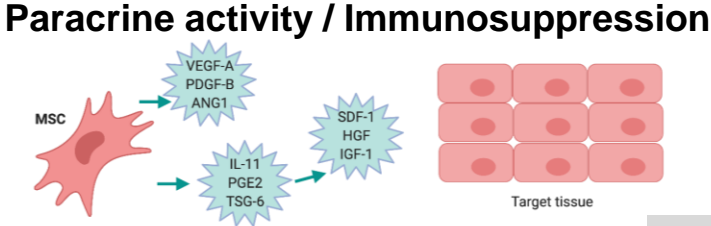
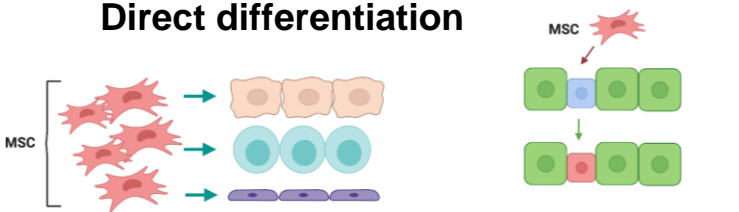
MESENCHYMAL STEM CELLS

- They have immunomodulatory (immunosuppressive) effects both in vitro and in vivo
- They do not elicit a rejection immune response in allogeneic transplantation
- MSCs affect almost all of our immune cells
- They play a key role in the development of tissue tolerance and homeostasis



Li, N. and Hua, J. 2016. Interactions between mesenchymal stem cells and the immune system, *Cell. Mol. Life Sci.* (2017) 74:2345–2360
 Kun-Varga, Anikó ; Kemény, Lajos ; Végh, Edit ; Szamosi, Szilvia ; Csomor, Péter ; Szekanez, Zoltán ; Veréb, Zoltán. 2020. Mesenchymális őssejtek immunológiai tulajdonságai, *Immun. Szem.* (2020) 12(3) : 51-71

MSC - CLINICAL APPLICATION

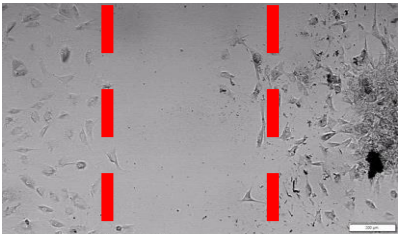


Mesenchymal stem cell (MSC)

1327 clinical study

Phase I: 754 study
 Phase II: 670 study
 Phase III: 79 study
 Phase IV: 7 study

Potential uses of Stem cells

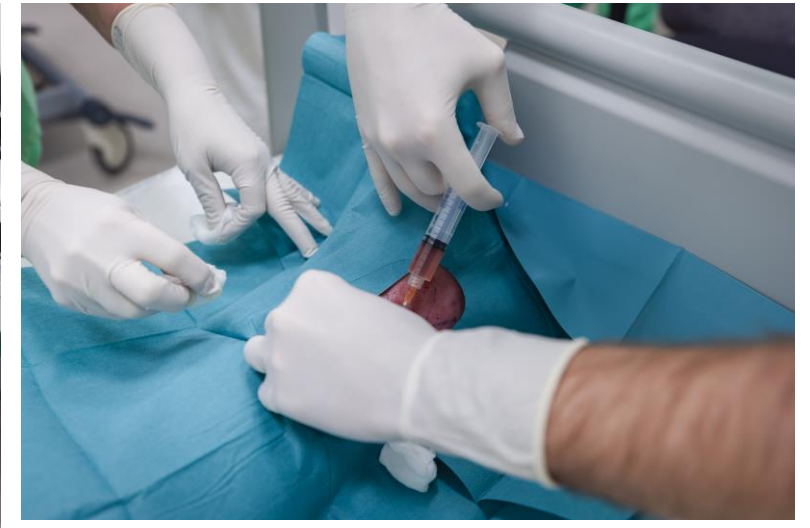


WOUND HEALING TEST (ADMSC)

CLINICAL PHASE I. TRIAL – SVF TREATMENT FOR NON-HEALING ULCERS

INCLUSION CRITERIA

1. Written informed consent
2. Males or females age ≥ 18
3. At least one venous chronic leg ulcer with the following condition
 - 3.1 Ulcer is present beyond 2 months
 - 3.2 Conservative treatment not leading to improvement
 - 3.3 Wound size between ≥ 5 and ≤ 100 cm²
4. Ability to safely undergo tissue harvest that is anticipated to yield >100 mL of adipose tissue at a site that is free from infection and injury



CLINICAL PHASE I. TRIAL – SVF TREATMENT FOR NON-HEALING ULCERS

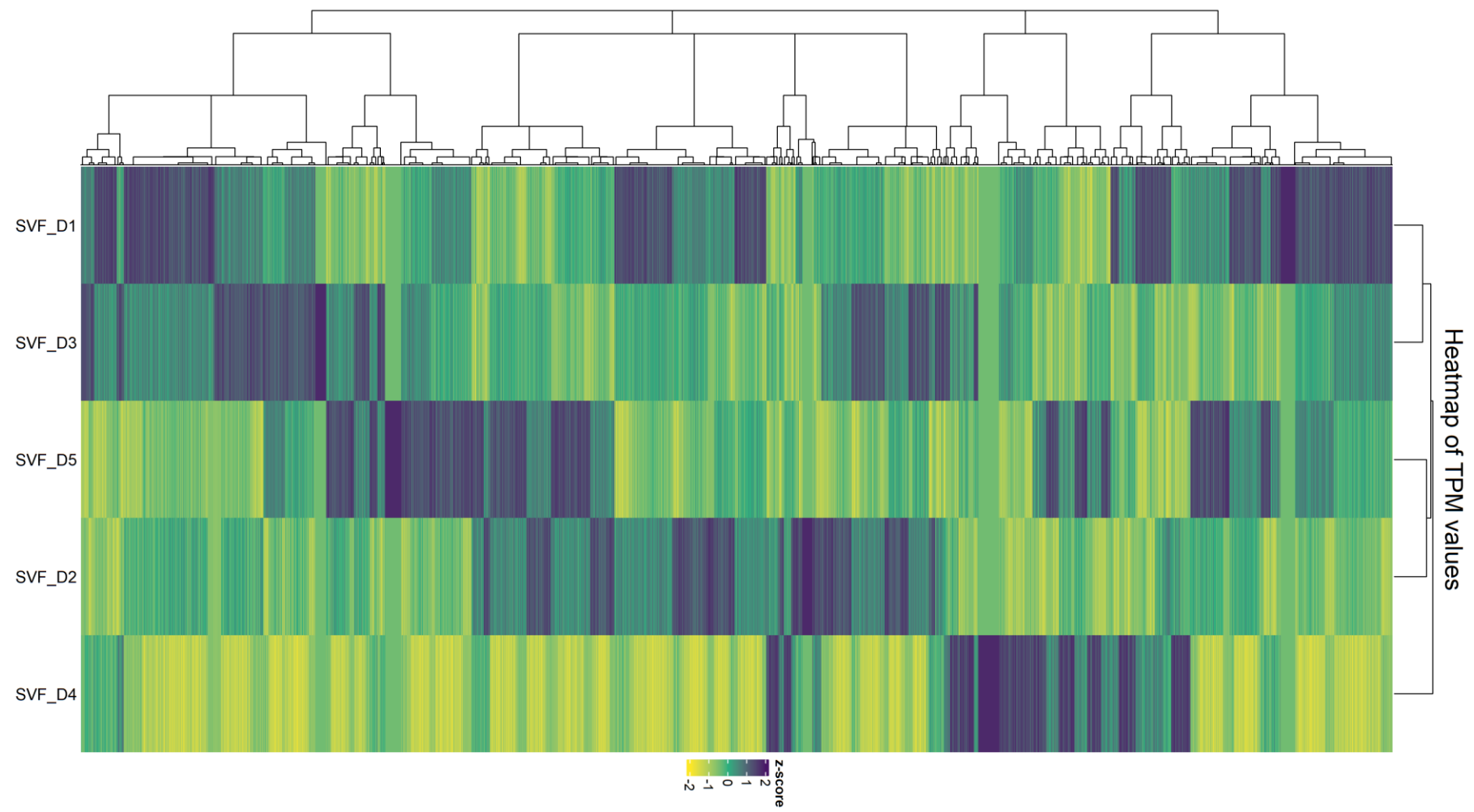


CLINICAL PHASE I. TRIAL – SVF TREATMENT FOR NON-HEALING ULCERS



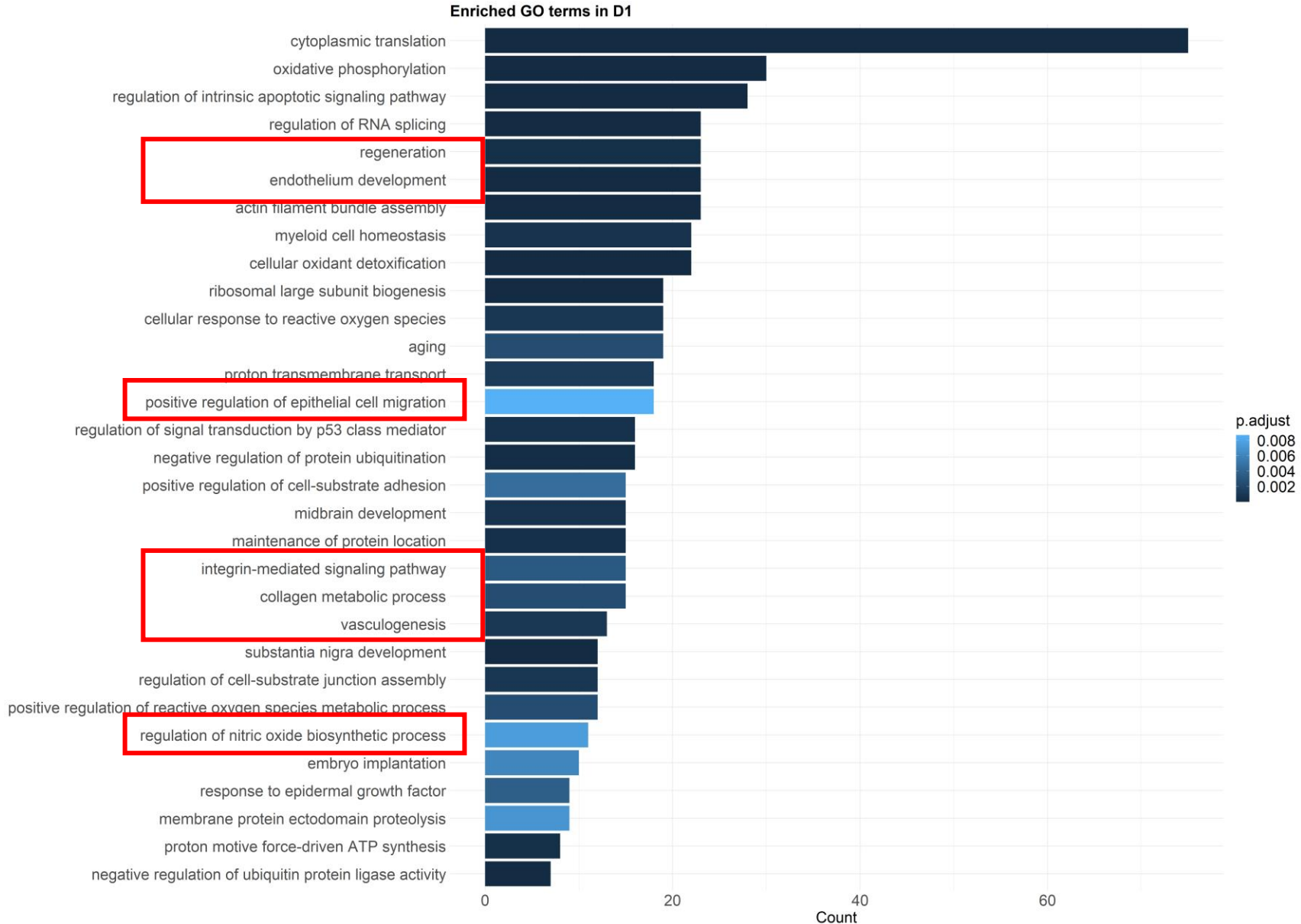
CLINICAL PHASE I. TRIAL – SVF TREATMENT FOR NON-HEALING ULCERS

GENE EXPRESSION PROFILE OF SVF DONORS



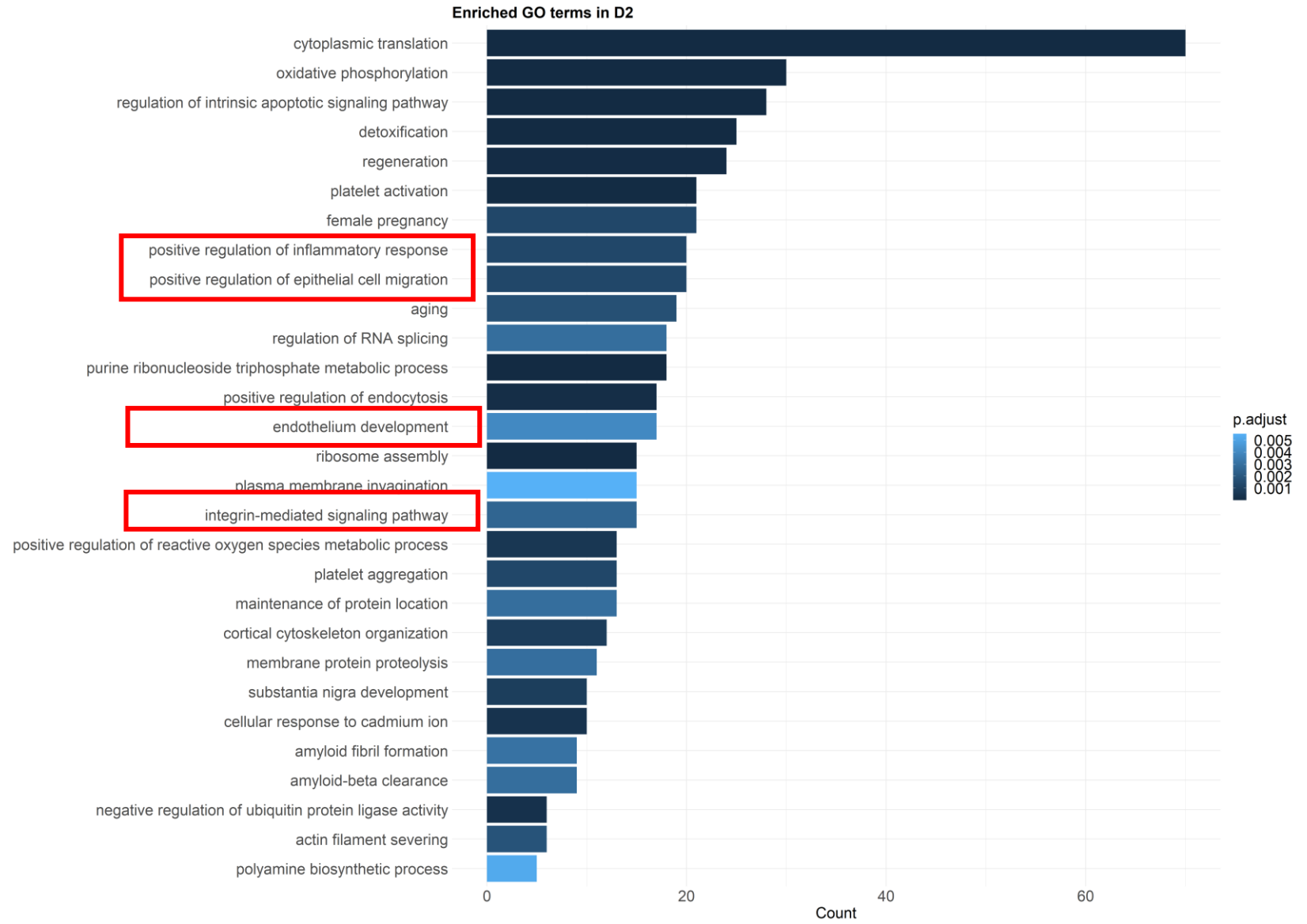
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GENE EXPRESSION PROFILE OF SVF DONORS



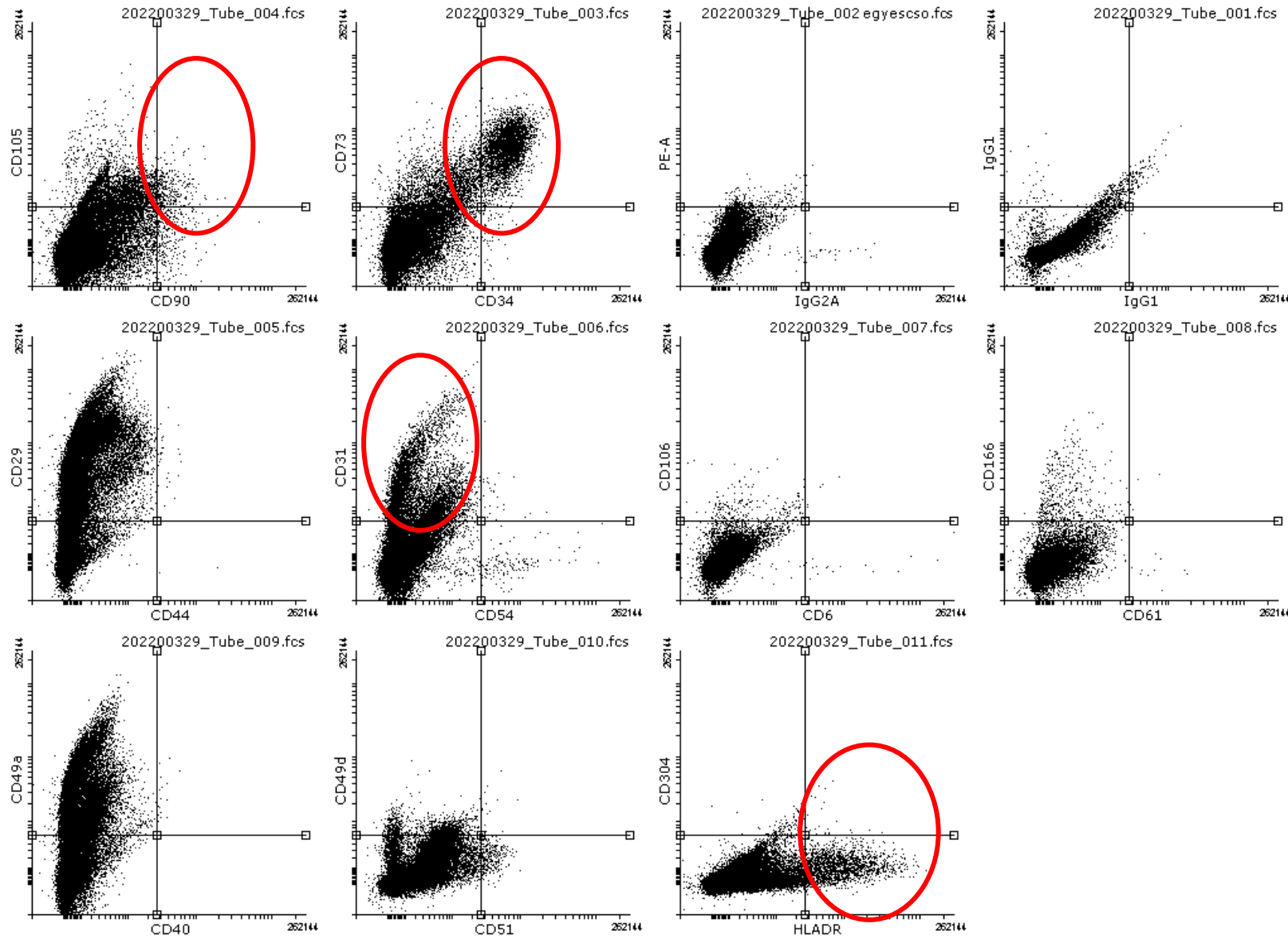
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GENE EXPRESSION PROFILE OF SVF DONORS



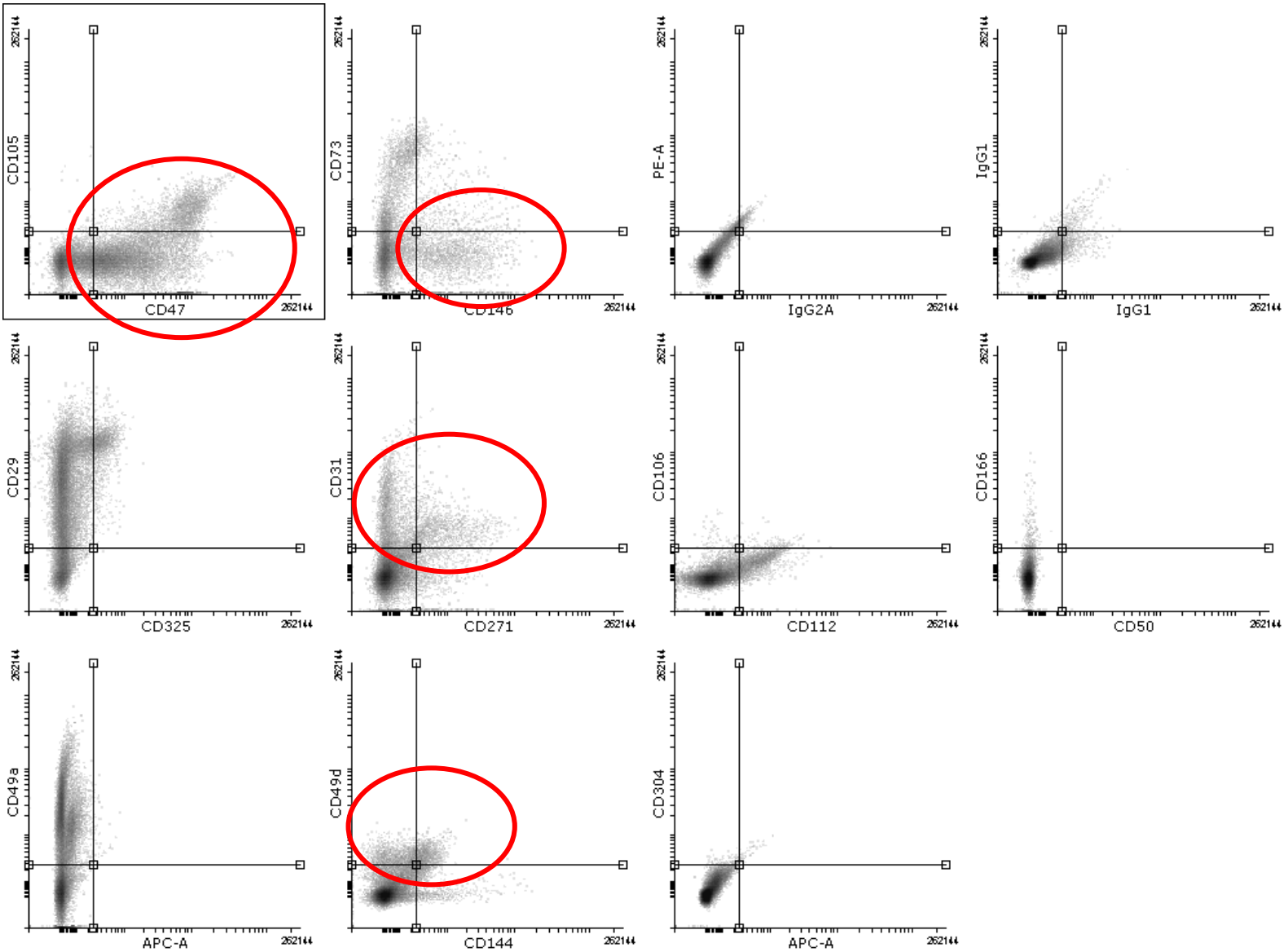
CLINICAL PHASE I. TRIAL – SVF TREATMENT FOR NON-HEALING ULCERS

PHENOTYPE OF SVF (CTP)

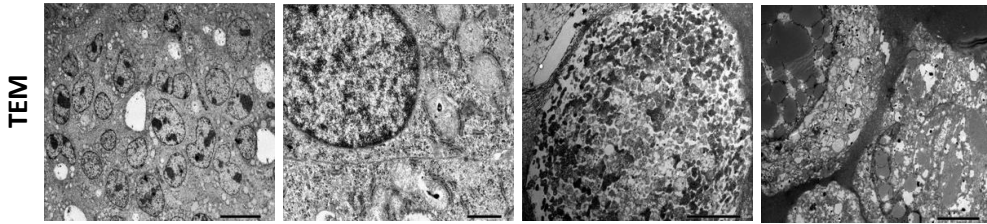
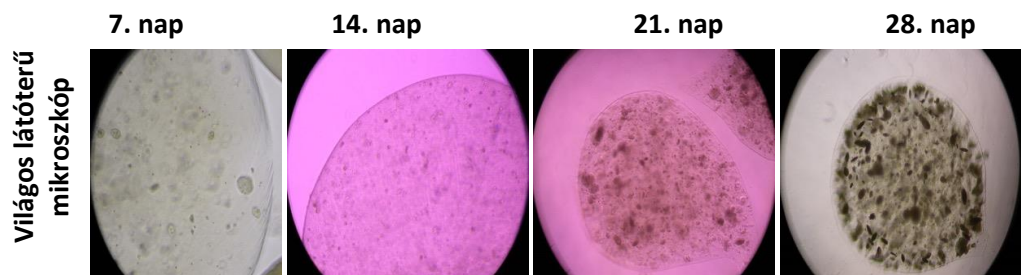


CLINICAL PHASE I. TRIAL – SVF TREATMENT FOR NON-HEALING ULCERS

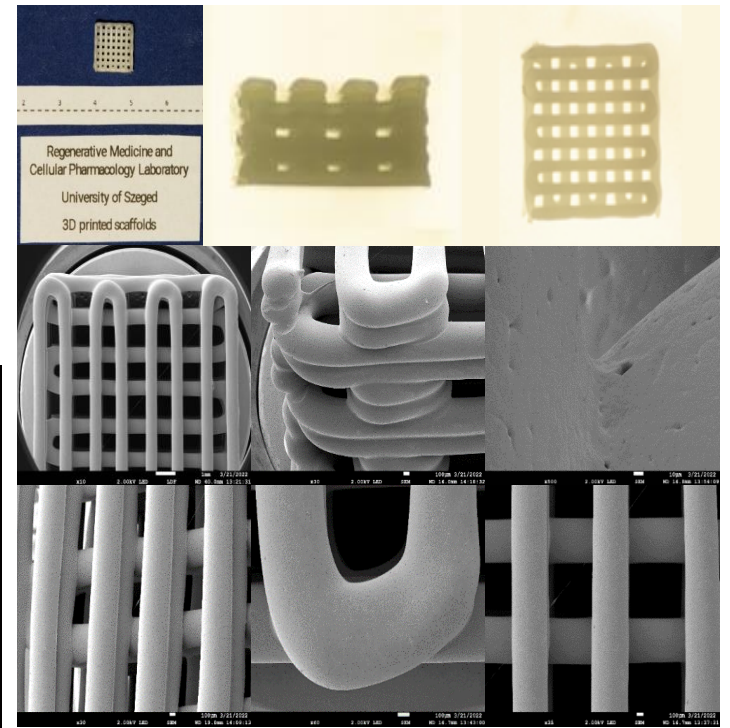
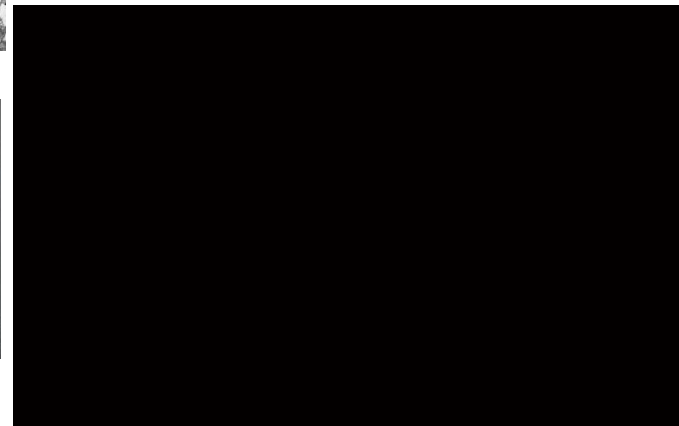
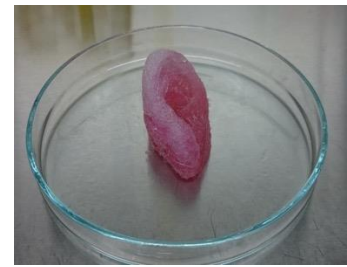
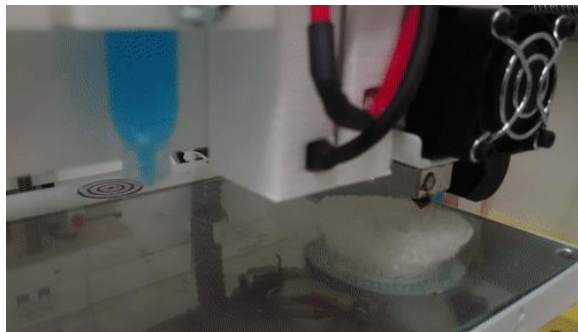
PHENOTYPE OF SVF (CTP)



3D BIOPRINTING



HepG2 3D spheroidok



THANK YOU FOR YOUR ATTENTION



Diána Szűcs



Tamás Monostori



Katalin Boldog



Borbála Lovászi



Prof. Dr. Lajos Kemény



Melinda Guba



Shahram Parvaneh



Dr. Balázs Bende

THANK YOU FOR YOUR ATTENTION



PROJECT
FINANCED FROM
THE NRDIFUND

