Regenerative Medicine in Healthcare
Policy of the Abe Administration

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The first transplant of RPE cell sheet in derived from iPS cells
The main points of the Act on Promotion of Healthcare Industries and Advancement of Healthcare Technologies

Establishment of the Headquarters of Healthcare Policy (HHP) [Article 21 through 29]

The Healthcare Policy (Article 17)
The Prime Minister shall seek a cabinet decision on the Healthcare Policy, which consists of the following points:
✓ Promotion of medical R&D, preparation of R&D environment, and dissemination of the results of R&D
✓ Creation and vitalization of new businesses and industries including export of Japanese healthcare systems and medical equipment

The Plan for Promotion of Medical R&D (Article 18)
The HHP shall make the plan which shall include the following points:
✓ Decision on important fields of medical R&D in which the Government should focus its resources
✓ Functions of the AMED that shall play core roles in implementation and in granting of medical R&D

The HHP shall propose a basic policy of the management of the business of the A-MED based on the Plan for Promotion of Medical R&D

Japan Agency for Medical Research and Development, independent administrative agency (AMED)
Japan Agency for Medical Research and Development Agency (AMED)

Promote and support medical R&D consecutively from basic research to clinical research/trial by funding

- Strong management of R&D program by PD, PO and etc.
- Improvement of the infrastructure for clinical research/trial
- Support for industrialization; bridging academia and industry
- Promotion of International strategy

9 Projects supported by 3 Ministries:

1. Drug discovery
2. Medical devices
3. Infrastructure of clinical research and trial
4. Regenerative medicine
5. Genomic Medicine
6. Cancer
7. Psychiatric and Neurological Disorders (Brain research)
8. Emerging and re-emerging infectious diseases
9. Intractable diseases
Current Situation on International Center supported by Government of Japan

HOKUTO Imaging Diagnosis Center (Vladivostok)
May, 2013
Hokuto Hospital

Cambodia Emergency Medical Center (Phnom Penh)
Under construction
Kitahara International Hospital

Sakra World Hospital (Bangalore)
March, 2014
SECOM Medical System and TOYOTA Tsusho

Other cases such as in Kazakhstan, Vietnam, Indonesia, Myanmar, Kuwait, Qatar, Brazil etc. are under consideration.
Regenerative Medicine Highway
Promoted by AMED
Risk-based classification of regenerative medicine practice under the Act to Ensure the Safety of Regenerative Medicine

Category I: High Risk (ES cells, iPS cells etc.)
- Medical Institution Application
- Certified Special Committee Review
- Submission to MHLW
- 90 days review
- Change Order
- MHLW Opinion
- Council
- Practice

Category II: Medium Risk (Somatic stem cells etc.)
- Medical Institution Application
- Certified Special Committee Review
- Submission to MHLW
- Practice

Category III: Low Risk (processed somatic cells etc.)
- Medical Institution Application
- Certified Committee Review
- Submission to MHLW
- Practice
New Approval System under the Pharmaceuticals and Medical Devices Act (PMD-Act)

Traditional Approval Process:
- Pre-Clinical Research
- Clinical Trial (confirmation of efficacy and safety)
- Approval
- Marketing

New Scheme for Regenerative Medical Products:
- Pre-Clinical Research
- Clinical Trial
- Conditional/time limited authorization
- Marketing (further confirmation of efficacy and safety)
- Re-Application
- Approval or Expiration of Conditional/Time-limited Authorization
- Marketing

Informed Consent and Post Market Safety Measures

* Earlier Patient Access!

* Probable benefit: Confirmation of efficacy with small patient population.
** Safety: Evaluation of acute adverse events etc.
Thank you very much for your attention!