Perspective

Policy Roadmap for Stem Cell Technology in Thailand

Sorapop Kiatpongsan MD*,**,***

** Department of Obstetrics and Gynecology, Faculty of Medicine, Chulalongkorn University, Bangkok, Thailand*
*** Vincent Center for Reproductive Biology, Department of Obstetrics, Gynecology and Reproductive Biology, Massachusetts General Hospital, Harvard Medical School, Boston, MA, USA*
**** Belfer Center for Science and International Affairs, Kennedy School of Government, Harvard University, Cambridge, MA, USA*

Policy and technology roadmaps have been long and widely used in industry and business sectors. The primary objective of the roadmap is to be a policy and technology planning tool helping to deal with an increasingly competitive environment. The obvious benefit of roadmapping is to provide information to make better technology investment decisions by identifying critical technologies and technology gaps and identifying methods to improve research and development (R&D) investments. It can also be used as a marketing tool. Roadmapping is critical and necessary when the technology investment decision is not straight forward. This occurs when it is not clear which alternative to pursue, how soon the technology is needed, or when there is a need to coordinate the development of multiple technologies. Stem cell technology is still in its nascent stage and one of the technologies with obvious uncertainties. Moreover, it involves many issues from bioethical, legal and public policy perspectives. Then, development of national policy and technology roadmap for stem cell technology is definitely required and crucial to make most benefit from this promising technology for Thailand. The present article will provide perspectives on stem cell policy roadmap and propose critical action plans for the next five-year period.

Keywords: *Stem cells, Regenerative medicine, Policy roadmap, Technology roadmap, Thailand*

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Correspondence to : Kiatpongsan S, Department of Obstetrics and Gynecology, Faculty of Medicine, Chulalongkorn University, Rama 4 Rd, Pathumwan, Bangkok 10330, Thailand. E-mail: ksorapop@yahoo.com

Definition

From Merriam-Webster Online dictionary:

Roadmap: A detailed plan to guide progress toward a goal.

Policy: A definite course or method of action selected from among alternatives and in light of given conditions to guide and determine present and future decisions or a high-level overall plan embracing the general goals and acceptable procedures especially of a governmental body.

Technology: A practical application of knowledge especially in a particular area or a capability given by the practical application of knowledge.

One of the practical working definitions of policy/technology roadmap was proposed by Robert Galvin, the Chairman and CEO of Motorola in 1998:

"A roadmap is an extended look at the future for a chosen field of enquiry composed from the collective knowledge and imagination of the brightest drivers of change in that field. Roadmaps

communicate visions, attract resources from business and government, stimulate investigations and monitor progress. They become the inventory of possibilities for a particular field…"

Stem Cell Technology and Policy Roadmap

Stem cell technology is still in its nascent stage and one of the technologies with obvious uncertainties. Moreover, it involves many issues from bioethical, legal, business and public policy perspectives. Then, development of policy and technology roadmap for stem cell technology is definitely required and crucial to make most benefit from this promising technology.

The United Kingdom (UK) is one of the leaders in establishing and using a policy roadmap for various technologies. The clear vision and long-term plan have made the UK at the forefront of stem cell technology and draw great investment and resources from all over the world. The overview picture of stem cell roadmap in UK is shown in Fig. 1.

Stem Cell Technology in Thailand

Since Thailand has good potentials (basic infrastructure, human resource and a medical tourism program) for basic biomedical research, biotechnologies and medical innovations, stem cell and regenerative medicine would be another promising area that will be beneficial for the country both for improving the quality of life of Thais by curing and alleviating many chronic and current incurable conditions and also for enhancing competitiveness in science and technology of Thailand both at regional and international levels.

It is then crucial to identify strength, weakness, opportunity and threat (SWOT analysis) for stem cell technology in Thailand.

Strength

• National organization on biotechnology, for example, National Center for Genetic Engineering and Biotechnology (BIOTEC), National Science & Technology Development Agency (NSTDA)

• National stem cell bank established under the supervision of the Thai Red Cross Society

• Clinical-grade vaccine production unit under the supervision of Thai Red Cross Society

• *In vitro* fertilization (IVF) centers that have a lot of frozen embryos that will be an essential resource for new human embryonic stem cell (hESC) line derivation

• Good quality health care at a lower cost compared with western countries; Thailand has proposed to be a medical hub for South East Asian and Asian areas

Weakness

• Lack of national-level long-term policy and technology roadmap for stem cell technology

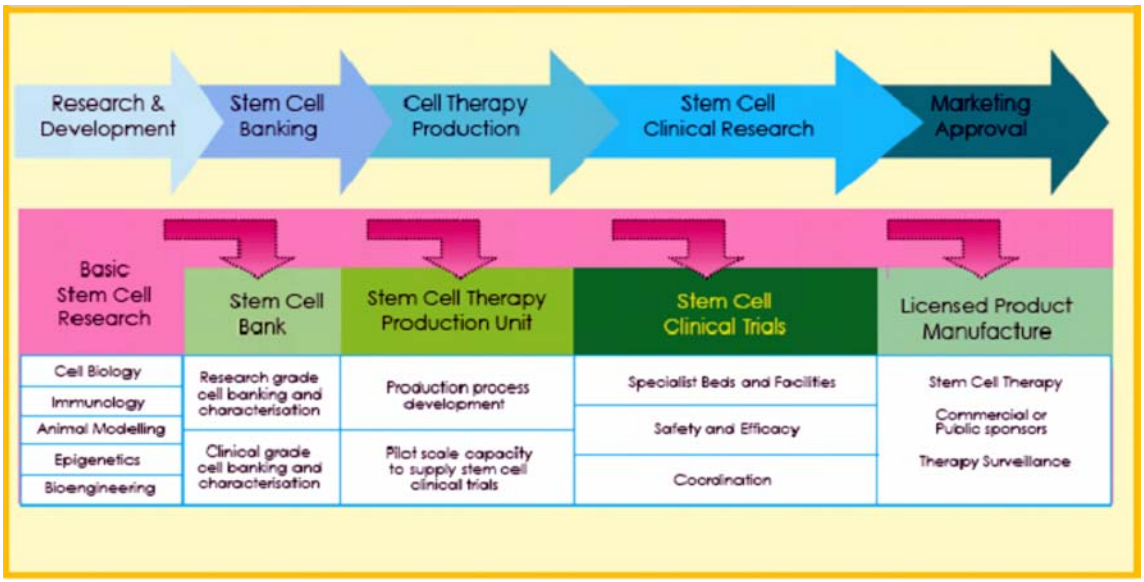

Fig. 1 The overview of UK stem cell policy roadmap[1]

• Lack of expertise in basic stem cell biology

• Lack of comprehensive database of researchers and research groups doing stem cell research in Thailand

• Lack of government-business partnership and venture capital investment on stem cell technology

• Lack of clear regulatory and oversight system

Opportunity

• Regional leadership in South East Asia/Asia

• Increased potential and capability of the national stem cell bank

• Development of clinical-grade stem cell therapy production unit

• South East Asia regional center for education and training of stem cell biologists

Threat

• Singapore, China, and South Korea as potential leaders in the Asia region

• 'Brain-drain' to foreign countries that have better infrastructure and funding support

• Intellectual property captured in other countries

• Need to import advanced technology with expensive long-term maintenance cost

• Clinical trials without scientific basis will damage the reputation and reliability of the whole biomedical research community with adverse reaction and complications

Action plans in the next 5-year period (2007-2011)

The author as an investigator for the project National Policy Roadmap for Stem Cell Technology in Thailand has proposed 10 action plans needed to be accomplished to enhance Thailand's capability and competitiveness in stem cell technology (Fig. 2).

These topics are interrelated and need great coordination and contribution from many organizations and institutes:

National policy

There should be a national level policy plan for stem cell technology. This should be an immediate to long-term (5-10 years) plan developed with agreement of all the stakeholders. Having a national policy would provide a clear vision of the country that would benefit both scientific and business development.

Government-business partnership

As stem cell research requires more funding support compared with other biomedical research areas, business partnership would help to increase funding and direct the goal of the research toward clinical applications and enhance business value of research products. There should be some mechanisms

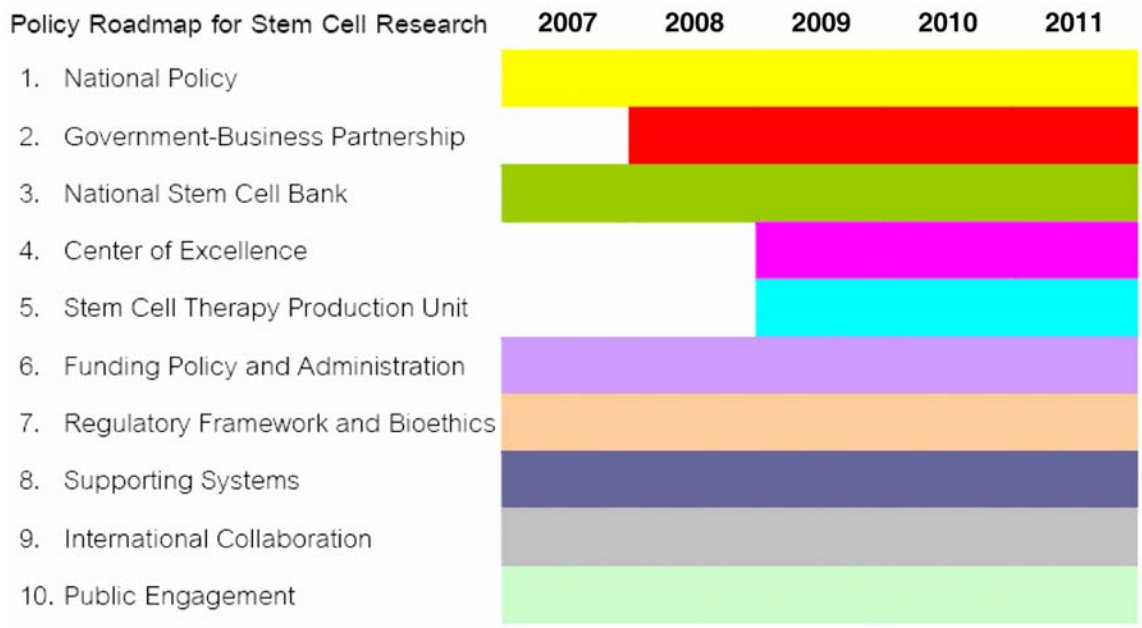

Fig. 2 Action plans proposed for the next five year period (2007-2011)

to promote and stimulate the formation of a government/ academia-business partnership.

National stem cell bank

A national stem cell bank would be an important resource center to provide research materials to all the research groups in Thailand. In the future, a stem cell bank would be a central storage and distributor of cells and tissues for therapeutic purpose. In addition, a national stem cell bank could be a reference and training center. Then, enhancing potential and capability of a national stem cell bank is needed and crucial for future stem cell technology.

Center of excellence

As the resource is limited, there should be a special strategic plan to promote a promising and outstanding stem cell research center to be the center of excellence. Having a center of excellence will help to increase competitiveness of the country. In addition, this center would be a role model and reference center for other research groups.

Stem cell therapy production unit

To bring stem cell technology from the "bench" to "bedside" or into clinical practice, there should be a special facility, stem cell therapy production unit, established to make sure that material for therapy is qualified and safe. This facility must meet the good manufacturing practice (GMP) and other international standards for stem cell therapy.

Funding policy and administration

As funding is one of the key issues for stem cell research since this emerging technology needs more funding support compared with other biotechnologies, there should be a clear policy on funding administration and a special mechanism to help young investigators to access enough funding and resource needed for establishing their laboratories and performing good quality research.

Regulatory framework and bioethics

Since stem cell research, especially embryonic stem cell research, involves many sensitive bioethical issues, clear regulatory and oversight system is required and necessary. This is not only for preventing negative impacts from stem cell trials without scientific basis and misuse of human embryos but also promoting stem cell research overall by providing clear regulation to both researchers and business investors. This regulatory and oversight system should be "flexible" for updating and modification since stem cell knowledge is changing rapidly and is very dynamic.

Supporting systems

There should be supporting systems for stem cell research and development. For example, there should be a database and mapping of stem cell researchers in Thailand. This database should include but not limit to research interest, research expertise and a research team. This would be invaluable information for making consultation and collaboration among groups in Thailand. There should be support and help provided on patent, intellectual property and business issues since these are complicated for stem cell technology.

International collaboration

There should be a system to promote and support international collaboration since this would be a key for technology and knowledge transfer. The international collaboration may be promoted through an educational workshop, human resource training and research collaboration. There should be a clear and practical policy on stem cell material transfer between countries.

Public engagement

This would be promoted primarily by public education. The general public should obtain accurate and update information both on technology itself and related bioethical issues. This would eventually raise public concern, involvement and support "sustainable" development of science and technology together with development of society.

Current consensus and future plan

There was a meeting at the National Center for Genetic Engineering and Biotechnology (BIOTEC) in March 2007 to brainstorm experts' opinion and finalize the plan for developing national policy roadmap for stem cell technology. There was an agreement on the necessity and importance of having the national-level policy roadmap. There was a concern on the lack of clear regulatory and oversight system. This was raised as an urgent issue. There was an idea to create a national network of stem cell researchers in Thailand. The follow up work would be prioritizing the action plan and establishing working groups responsible for each topic. Involvement and agreement from all the stakeholders would be very important and crucial

factors for the success of roadmap development with the final goal to establish and get most benefit from stem cell technology in Thailand.

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Reference

1. UK Stem cell initiative: report & recommendations. November 2005. Available at: http://www.advisorybodies.doh.gov.uk/uksci/

แนวนโยบายเทคโนโลยีเซลล์ต้นกำเนิดในประเทศไทย

สรภพ เกียรติพงษ์สาร

แนวนโยบายและแผนที่ทางเทคนิคมีการพัฒนาสร้างขึ้นและถูกนำมาใช้อย่างแพร่หลายในแวดวงอุตสาหกรรมและธุรกิจ โดยมีวัตถุประสงค์หลักเพื่อเป็นการวางแผนอนาคต ในภาวะที่มีการแข่งขันสูง อีกทั้งยังช่วยในการตัดสินใจเลือกการลงทุนโดยพิจารณาถึงเทคโนโลยีที่สำคัญ เป็นการพิจารณาถึงช่องโหว่และกระบวนการที่จะส่งเสริมกระบวนการวิจัยและพัฒนาขององค์กร รวมทั้งจะสามารถช่วยในการวางแผนเพื่อการตลาด การพัฒนาสร้างแนวทางแผนที่อนาคตทั้งในเชิงนโยบายและเทคนิคมีความสำคัญและจำเป็น ในกรณีที่การตัดสินใจลงทุนมีความสลับซับซ้อน มีความยากในการตัดสินใจเลือกแนวทางในการดำเนินการ ทั้งในแง่ระยะเวลาและเทคโนโลยีย่อยที่เหมาะสม อีกทั้งในกรณีที่ต้องมีการผสมผสานระหว่างหลายเทคโนโลยีเข้าด้วยกัน

เนื่องจากเทคโนโลยีเซลล์ต้นกำเนิดยังอยู่ในระยะแรกเริ่ม มีความสลับซับซ้อนและมีแนวทางเลือกมากในการดำเนินการ รวมทั้งความไม่แน่นอนในหลายระยะของการพัฒนาการ ตลอดจนมีความเกี่ยวข้องกับหลายประเด็นทางชีวจริยธรรม กฎหมาย และนโยบายสาธารณะ การพัฒนาสร้างแนวนโยบายและแผนที่อนาคตทางเทคนิคในระดับชาติจึงมีความสำคัญและจำเป็นเพื่อนำเทคโนโลยีนี้มาใช้ให้เกิดประโยชน์สูงสุดกับประเทศไทย บทความนี้นำเสนอถึงแนวทางการพัฒนาสร้างแนวนโยบายเซลล์ต้นกำเนิดของประเทศไทย และกระบวนการสำคัญที่ควรดำเนินการในช่วงระยะ 5 ปี
