

座談会 〈Round table discussion〉

## わが国の臨床研究と 医療イノベーションの今後を見据えて

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## Reformation of clinical research and medical innovation policies in Japan: Challenges and opportunities

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### Abstract

In Japan, drastic regulatory reformation of Pharmaceutical Affairs Law and development of new laws and regulations for regenerative medicine have been recently achieved. The Prime Minister and his Cabinet have established an office to push forward outstanding medical research innovation and launched a “control tower” to ensure integrated research management.

Here we discussed about landmark issues on policy reformation and actual situations of progress in innovative clinical research as well as research management frameworks for promoting state-of-the-art health technologies. The policies and research governance frameworks discussed here will provide traction to overcome people's distrust, restore confidence in Japanese clinical research, and finally, enable Japan to contribute to global health.

### Key words

Prime Minister and his Office, Pharmaceuticals and Medical Devices Agency (PMDA), Translational Research Network Program, molecular imaging, Good Clinical Practice (GCP)

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