

# Recommendations for Physician Innovators

See also CMA Policy [Guidelines for physicians in interactions with industry](#)

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Physicians are increasingly taking on leadership roles in medical innovation or entrepreneurship enterprises, or are embedded in industry leadership and development teams — roles that place the physician *within* industry.<sup>a</sup> Physician innovators are in a unique position as both members of industry and medical professionals with primary ethical and professional obligations to patients, the public, and the profession.

This document provides recommendations to help guide physician innovators across the career life cycle in navigating their roles as medical professionals who are also directly engaged in medical and health care innovation.<sup>b</sup> These recommendations serve as a companion document to the *Guidelines for Physicians in Interactions with Industry* (GPII), which offer direction on how physicians should interact with industry when an arm’s-length relationship exists, including as consultants, as advisors, or as recipients or users of industry funding, products, or information. The GPII continue to apply to physician innovators within their roles as clinicians, educators, and researchers when interacting with industry. Physician innovators and the relationships

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<sup>a</sup> In these recommendations, industry refers to health-related industries, which include, but are not limited to, manufacturers, developers, or suppliers of pharmaceuticals, therapeutics, medical devices and supplies, health care products and services, wellness and nutritional products and services, biotechnology, information technologies including software (such as for the management of patient data, records, and treatment), and products that may be understood as having a clinical or health benefit.

<sup>b</sup> The WHO Health Innovation Group (2016) defines health innovation as follows: “Health innovation is to develop new or improved health policies, systems, products and technologies, and services and delivery methods that improve people’s health, with a special focus on the needs of vulnerable populations.” The term “physician innovator” is used in this document to describe physicians when performing these roles. Examples include, but are not limited to, owning and licensing an innovation; founding, owning, or holding a financial interest in a health innovation business; holding an executive position in, or sitting on the board of, a business involved in health innovation; and participating in health-related product, device, or software development.

between physicians and industry are also guided by the [CMA Code of Ethics and Professionalism](#). A fundamental commitment of the medical profession in the Code is the commitment to professional excellence, which includes contributing to the development of, and innovation, in medicine.

Innovation can benefit patients, society, and physicians through the advancement of medical science and practice, effective, and safe use of health care products, devices, and services, and ultimately by improving patients' opportunities to access the benefits of health care and better health outcomes. With their medical knowledge, skills, and experience, physicians are well placed to contribute to innovation. However, physician innovators' direct interest in their activities and innovations creates a unique potential for conflicts of interest. Evidence indicates that physicians may not always be aware of, or be able to accurately self-assess, how their industry participation can influence their judgment, even subconsciously, when assessing or presenting medical evidence.

Physicians have a responsibility to ensure that their health-related innovation activities primarily serve the interests of their patients and the public. Physicians must strive first to avoid or secondly to minimize or manage conflicts of interest. They must always disclose any innovation activities that have, or could be perceived as having, the potential to influence their judgment, including their professional recommendations, clinical decisions and prescribing.

Physicians should also be aware of regulatory or legal requirements that govern medical practice and the use of patients' personal health information in the jurisdiction where they practice and any additional requirements set out by relevant institutions, research ethics boards, accreditors, and publishers, which may be more stringent than these recommendations.

## GUIDING PRINCIPLES

These principles apply both to these recommendations and to the [Guidelines for Physicians in Interactions with Industry](#). These principles draw on the [CMA Code of Ethics and Professionalism](#).

### Well-being of the patient

A physician's primary obligation is to preserve and promote the well-being of the patient. Relationships with industry are appropriate only where they do not undermine the physician's duty of loyalty to protect and further the patient's best interests and goals of care. Physicians must resolve any conflict of interest between themselves and their patient resulting from interactions with industry in favour of the patient. In particular, they must avoid acting in self-interest in their prescribing and referral practices.

### Public trust

Trust is central to the patient–physician relationship and to providing the highest standard of medical care. Patients and the public should be able to trust that physicians prioritize the well-

being of patients above all else. Physicians involved in innovation or with industry must uphold patients' and the public's trust in physicians, in the profession of medicine, and in medical science. Transparency helps promote public trust by facilitating oversight and accountability, as well as facilitating public commentary and advocacy.

### Professional integrity

Physicians must uphold professional integrity when engaging in innovation or entering into associations, contracts, and agreements with industry. Integrity requires maintaining professional autonomy and independence, acting in accordance with professional expectations and the best available medical evidence, adhering to scientific methodology, and safeguarding the interests of the patient or public. Professional integrity also requires humility, honesty, and the transparent disclosure of innovation activities and industry relationships to patients, colleagues, and supervisors when such potential conflict would be viewed by others as relevant to the relationship in question.

### Social accountability and equity

Social accountability is central to professional excellence in medicine. Physicians and the profession express social accountability when they respond to the current and future priority health needs of the patients and communities that they serve in their clinical practice, education, research, leadership, and advocacy. Physician interactions with industry and physician-led innovation should be guided by a primary concern for advancing the health and addressing the evolving health needs of Canadians, including by advancing medical practice and science to reduce health inequities and disparities in care.

## RECOMMENDATIONS

### Avoiding and managing conflicts of interest

1. Conflicts of interest arise when a person in a position of trust has competing professional or personal interests. Conflicts of interest occur where judgments or decisions about a primary interest — in this case, patient well-being, trustworthy medical research and knowledge, and excellent medical education — are unduly influenced by a secondary interest. Secondary interests can include direct financial gain, professional advancement, and reputational benefits, or other benefits to family, friends, or colleagues. Conflicts of interest may be real, potential, or perceived, and may exist even if no unethical or inappropriate act results from the conflict. Physician innovators may benefit in various ways as a result of their innovation activities, including through holding equity in, or benefiting financially from, their innovations. Conflicts of interest may arise in the context of competing roles that physicians hold (such as clinical, education, research, organizational, administrative, leadership, or advocacy roles).
2. Physician innovators must *ensure* that their activities do not inappropriately affect their medical judgment and practice (including how they diagnose, prescribe, treat, or refer treatments or services for patients) in ways that do not support the well-being of their patients. They should recognize that an ownership or an equity interest in their innovation increases the likelihood of having a conflict of

interest and the complexity of that conflict.

3. Physician innovators must *identify* any real, potential, or perceived financial and non-financial conflicts of interest that may arise as a result of their role as an innovator in the context of medical practice, education, or research. They should carefully deliberate over the impact of these conflicts of interest and determine whether these conflicts can be managed so that they do not affect the physician's medical practice in ways that do not support the well-being of their patients. If the conflict cannot be managed, the physician should seek to separate their innovation activities from their clinical practice, education, and research activities. Physician innovators are encouraged to consult with a colleague or peer when evaluating a potential conflict of interest.

4. Physician innovators must *disclose* any innovation-related activities (such as innovation-related financial or equity and reputational interests) that may pose a real or perceived conflict of interest when providing patient care, offering recommendations to colleagues, or carrying out other activities related to their role as a physician. Disclosures should be made to anyone who might be affected by a real or perceived conflict.

5. As they can play an industry-like role, physician innovators should be mindful that their innovation activities may place other health care professionals, learners, and institutions in a conflict of interest. Physician innovators must disclose their innovation activities and work with professionals, learners institutions, and patients to avoid or manage conflicts of interest and to make others aware of potential conflicts.

6. Physician innovators must recognize that disclosure alone does not necessarily eliminate or fully mitigate a conflict of interest. Physician innovators should consider using additional tools to facilitate managing or avoiding conflicts of interest, including documenting deliberations, developing a written conflict of interest management plan, and consulting colleagues or third-party experts for further deliberation and independent advice.

## Patient care

7. Physicians who wish to refer or recommend products or services outside of a clinical trial in which they have had a central development role should only do so if: (1) evidence supports using the innovation in practice; (2) it has undergone external, independent peer review or assessment; (3) it has been shown to be beneficial; and (4) a detailed, written conflict of interest management plan has been developed, which should include documenting their disclosure to the patient.

8. Where practical, physicians should direct patients to a colleague who can offer an unconflicted referral or second opinion regarding the use of a product or service in which they have had a central development role.

9. When using their innovation as a part of clinical practice or referring it to patients, physicians must discuss alternatives, present a balanced discussion of relevant medical evidence, and disclose their involvement in such a manner that patients do not feel pressured to accept their advice or use the innovation.

10. Physicians who wish to trial their innovation on their patients should only do so with the express consent of the patient, and, in the context of products in an experimental or research phase, only if the products have undergone ethics review by an independent ethics review board. Physicians should consider trialling their innovation through an independent colleague where it is practical to do so. Physicians must explicitly state that the provision of the patient's ongoing care does not depend on a patient's acceptance of the innovation.

11. Where an innovation is smaller in scale or in impact, taking all the steps outlined in this section may not be necessary. However, where there is any doubt, physician innovators should adopt a prudent approach and take the relevant steps outlined above to ensure that any conflict is avoided or managed.

The following factors should be considered when determining the measures that should be taken:

- the risk of harm to patients and the public;
- whether and to what extent the physician innovator might derive a personal benefit from the innovation's use, including payment from the patient or another source; and
- whether the innovation might be or has been commercialized.

### Professional excellence and integrity

12. All physicians should remain committed to scientific methodology and should base their decisions on evidence of safety and effectiveness.

13. When assessing the value of their innovation, physicians should seek independent oversight or review of their innovation (such as through independent peer review, by involving an independent third-party scientist overseer or data custodian) wherever possible.

14. Apart from when they cannot disclose proprietary information or trade secrets, physician innovators should be transparent about the innovation research and development processes (such as by making research protocols publicly available in advance).

15. Physicians should follow any required process and approvals relating to their innovation (such as approval processes for medical devices or applications).

16. Physicians should protect the privacy and confidentiality of all personal health information used in the development of their innovation in accordance with all applicable regulations and professional standards.

17. Physician innovators who publicly promote or communicate about an innovation in which they have had a development role should be careful to do so in a way that truthfully and transparently refers to peer-reviewed evidence, does not overstate benefits or understate harms, and does not mislead patients or others about the scope and impact of the innovation. Physicians should clearly and transparently disclose their involvement in all public communication, including via social media.

18. Physician innovators must disclose any personal benefit they may receive as a result of their activities when communicating about their innovation with colleagues.

### Social accountability and equity

19. Physician innovators are encouraged to engage in innovation that takes into account the health needs of patients and populations, as well as to advance medical practice and science to reduce health inequities and disparities in care. Physician innovators are encouraged to strive to develop innovations that have a meaningful or positive impact on patient or population health or offer improvements in the quality of health care delivery and systems.

20. Physician innovators must also be mindful that their innovations may inadvertently create or contribute to bias, discrimination, health disparities, barriers to access, or other inequities. Innovators, including those in artificial intelligence, big data analytics, and machine learning, should take all reasonable steps to adopt a rigorous design and implementation process to prevent or minimize harms.

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See also **CMA Policy** [Guidelines for physicians in interactions with industry](#)