Faculty of
Pharmaceutical Medicine
of the Royal Colleges of Physicians of the United Kingdom

Advancing the science and practice of pharmaceutical medicine for the benefit of the public

Good Pharmaceutical Medical Practice

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緒言

Good Pharmaceutical Medical Practice（良質な製薬医学のための原則）は、世界中で製薬医学に関わる全ての医師に期待される基準、行為、態度について、明確なガイダンスと方向性を与えるものです。The Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the United Kingdom (英国王立内科医協会　製薬医学分科会　以下 FPM)は、この文書で概説された原則を、世界中で製薬医学に従事しているすべての人々に提唱します。また、この GPMP は、FPM の会員規範を表すものでもあります。

Good Pharmaceutical Medical Practice は、国際および国内法令を補うものです。我々は、その基盤となるものとして Good Medical Practice （良質な医学のための原則）2013[viii] (GMC: 英国医事委員会)を採用しました。Good Pharmaceutical Medical Practice は、法令というよりはガイダンスであり、その目的は、製薬医学を専攻するあるいは製薬医学に関わる医師に対して追加の方向性を提供することにあります。**この文書内で青字のテキストが FPM によって追記されたものです。**

Good Pharmaceutical Medical Practice は、製薬医学における GMP の普遍的な基準をあらゆる状況下で満たすことを保証する為に作成されました。この Good Pharmaceutical Medical Practice は、Good Pharmaceutical Medical Practice (2008)[ix] と Guiding Principles for Pharmaceutical Physicians (2010)で最初に概説された原則を発展させたものです。また、2014 年に FPM が会員に対して行った臨床試験の透明性についてのサーベイ [xi]結果を反映しています。

製薬医学とは何か？

製薬医学とは、患者、社会そして公衆衛生への利益を理解し、推進するものです。製薬医学は、医薬品、診断法、医療機器の創出、開発、承認、倫理的なマーケティングや安全性を含みます。Good Pharmaceutical Medical Practice は、製薬医学と患者の関係を明確にするものです。患者の安全は、常に医師の第一の関心でなければなりません。製薬医学に関わる医師の多くは患者と直接かかわることが少ないが、製薬医学医師は、自らの行為によって影響を受けるすべての個人に対して責任があります。

製薬医学は、ヘルスケアについてグローバルなインパクトを与えます。アカデミックセンター、臨床薬理や治験ユニット、製薬やバイオテクノロジー企業、CRO、規制当局および開業医のような様々な環境下で製薬医学は行われます。また、製薬医学は、商業的な活動、人の管理そして経営上の活動も含むかもしれません。Good Pharmaceutical Medical Practice はこれらすべてのものに適応されます。製薬医学においては、ローカルで行われた決定は、グローバルに影響することもあれば、個別の国あるいは地域単位でのみ運用されることもあります。

なぜ追加的にガイダンスを作成するのか？

製薬医学に従事する医師は、すべての医師に適用される同じ倫理基準に従わなくてはなりません。しかし、製薬医学の業務は、臨床医学を目的として策定された一般的な倫理規範では十分に探求されていないような倫理的配慮が必要な特別な状況下にある場合があります。

全ての医師は、医療行為によるベネフィットと潜在的なリスクや副作用とのバランスを理解しなくてはなりません。しかし、製薬医学に従事する医師は、制限された情報しかない、そして関連する規制当局の承認をまだ受けていない実験的治療の開発に関わることがあります。これは、規制当局から承認を取得後、一般診療で長期間の使用が評価され、日常診療で使用されている医薬品とは異なります。従って、新規あるいは実験的治療の有効性と安全性のプロファイルは、更新され続けられるものであり、そのライフサイクルを通じて倫理的な管理が必要です。

Good Pharmaceutical Medical Practice は、FPM の会員のための行動規範です。従って、FPM の会員であれば、このガイダンスに従うことが期待されています。もし、FPM の会員でないが、製薬医学に関われる仕事をしている場合でも、このガイダンスを熟読しその原則に適合しているとかんがえています。*Good Pharmaceutical Medical Practice* は少なくとも国際的な法令を遵守すると考えます。しかし、法令への適合性だけでは十分ではありません。個人や公衆の健康を保護するためには、より高い基準のものが必須になってきます。

誠実さ、倫理性と製薬医学

いかなる業務にあたる場合にも、誠実さを貫くべき、すなわち最も高い倫理的原則と理想を硬く守るべきです。誠実さは、医学、教育そして倫理の実践の根幹です。*Good Pharmaceutical Medical Practice* は、医学研究と医療の実践において、社会に対する注意義務を含んでいます。適切なガバナンス組織において、倫理の実践、患者の安全そしてデータインテグリティなどに関して、十分に検討されなければならない。また、患者の擁護者して振舞わなければなりません。

この文書における”患者“の定義について

この文書を通して、“患者”という用語は、承認された、あるいは未だ承認されていない医療行為（臨床試験を含む）を受ける人々を示します。“患者”という用語は、健康ボランティアと疾患を持っている人の両方を意味するものとして使用します。

医療行為には、疾患の診断、治療あるいは予防に使用される医薬品が含まれます。医薬品という用語には、薬品、ワクチン、診断薬あるいは医療機器を含みます。

GMC の文書である *Good Medical Practice*[viii] は、特に患者のニーズに焦点を当てています。それ故、この文書の FPM により追記された注釈（青字のテキスト）においても、製薬医学の実践するために、患者第一という同じ原則に従います。

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The duties of a doctor registered with the General Medical Council

Patients must be able to trust doctors with their lives and health. To justify that trust you must show respect for human life and make sure your practice meets the standards expected of you in four domains:

Knowledge, skills and performance

- Make the care of your patient your first concern.
- Provide a good standard of practice and care.
    - Keep your professional knowledge and skills up to date.
    - Recognise and work within the limits of your competence.

Safety and quality

- Take prompt action if you think that patient safety, dignity or comfort is being compromised.
- Protect and promote the health of patients and the public.

Communication, partnership and teamwork

- Treat patients as individuals and respect their dignity.
    - Treat patients politely and considerately.
    - Respect patients' right to confidentiality.
- Work in partnership with patients.
    - Listen to, and respond to, their concerns and preferences.
    - Give patients the information they want or need in a way they can understand.
    - Respect patients' right to reach decisions with you about their treatment and care.
    - Support patients in caring for themselves to improve and maintain their health.
- Work with colleagues in the ways that best serve patients' interests.

Maintaining trust

- Be honest and open and act with integrity.
- Never discriminate unfairly against patients or colleagues.
- Never abuse your patients' trust in you or the public's trust in the profession.

You are personally accountable for your professional practice and must always be prepared to justify your decisions and actions.

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Professionalism in action

1. Patients need good doctors. Good doctors make the care of their patients their first concern: they are competent, keep their knowledge and skills up to date, establish and maintain good relationships with patients and colleagues,* are honest and trustworthy, and act with integrity and within the law.

製薬医学に関わる医師は、患者と直接コンタクトしないかもしれませんが、患者のニーズと福利を考えることを第一にしなければなりません。

2. Good doctors work in partnership with patients and respect their rights to privacy and dignity. They treat each patient as an individual. They do their best to make sure all patients receive good care and treatment that will support them to live as well as possible, whatever their illness or disability.

3. *Good medical practice* describes what is expected of all doctors registered with the General Medical Council (GMC). It is your responsibility to be familiar with *Good medical practice* and the explanatory guidance† which supports it, and to follow the guidance they contain.

Good Pharmaceutical Medical Practice に含まれる原則は、国際的に通用します。 製薬医学に従事する医師は、*Good Pharmaceutical Medical Practice* をよく理解し、従うべきです。

4. You must use your judgement in applying the principles to the various situations you will face as a doctor, whether or not you hold a licence to practise, whatever field of medicine you work in, and whether or not you routinely see patients. You must be prepared to explain and justify your decisions and actions.

5. In *Good Medical Practice*, we use the terms 'you must' and 'you should' in the following ways.

   'You must' is used for an overriding duty or principle.

   'You should' is used when we are providing an explanation of how you will meet the overriding duty.

   'You should' is also used where the duty or principle will not apply in all situations or circumstances, or where there are factors outside your control that affect whether or how you can follow the guidance.

Good Pharmaceutical Medical Practice は、法令ではなくガイダンスです。 しかし、この文書では、'あなたはしなければならない' と 'あなたはすべきである' という定義を上記（5）記載に従って適用します。 意思決定はしばしばチームによって行われます。患者の安全と福利に影響を与える可能性のある決定については、あなたはその決定にどのように関ったかのか？またその決定の正当性について説明する必要があります。

6. To maintain a licence to practise, you must demonstrate, through the revalidation process, that you work in line with the principles and values set out in this guidance. Serious or persistent failure to follow this guidance will put your registration at risk.

Good Pharmaceutical Medical Practice は、英国でのライセンス再審査の際に、Good Medical Practice の補助として用いるべきものです。それ以外の医師は、Good Pharmaceutical Medical Practice の原則を実務の正当性を判断する基準として用いるべきです。

* Colleagues include anyone a doctor works with, whether or not they are also doctors.
† You can find all the explanatory guidance on our website

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Domain 1: Knowledge, skills and performance

Develop and maintain your professional performance

製薬医学の実務に関連する 1 つ以上の専門団体の会員資格を保持するべきです。

7. You must be competent in all aspects of your work, including management, research and teaching.[1,2,3]

8. You must keep your professional knowledge and skills up to date.

9. You must regularly take part in activities that maintain and develop your competence and performance.[4]

10. You should be willing to find and take part in structured support opportunities offered by your employer or contracting body (for example, mentoring). You should do this when you join an organisation and whenever your role changes significantly throughout your career.

これは、自営および独立系の製薬医師にも当てはまります。

11. You must be familiar with guidelines and developments that affect your work.

12. You must keep up to date with, and follow, the law, our guidance and other regulations relevant to your work.

13. You must take steps to monitor and improve the quality of your work.

製薬医学では、「モニター」と「品質の向上」という用語は、監査、点検、その他のフィードバックなど、さまざまな形をとります。このフィードバックを良い行動と悪い行動の両方を判断し、良い方向への変化を学び促進するために利用すべきです。

Apply knowledge and experience to practice

14. You must recognise and work within the limits of your competence.

    14.1 You must have the necessary knowledge of the English language to provide a good standard of practice and care in the UK

Good Medical Practice には英語知識の要件が含まれていますが、あなたの実務にふさわしい言語スキルを持つことが、普遍的な原則です。

15. You must provide a good standard of practice and care. If you assess, diagnose or treat patients, you must:

    a. adequately assess the patient's conditions, taking account of their history (including the symptoms and psychological, spiritual, social and cultural factors), their views and values; where necessary, examine the patient

    b. promptly provide or arrange suitable advice, investigations or treatment where necessary

    c. refer a patient to another practitioner when this serves the patient's needs.[5]

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16. In providing clinical care you must:

    a. prescribe drugs or treatment, including repeat prescriptions, only when you have adequate knowledge of the patient's health and are satisfied that the drugs or treatment serve the patient's needs[6]

    b. provide effective treatments based on the best available evidence

    c. take all possible steps to alleviate pain and distress whether or not a cure may be possible[7]

    d. consult colleagues where appropriate

    e. respect the patient's right to seek a second opinion

    f. check that the care or treatment you provide for each patient is compatible with any other treatments the patient is receiving, including (where possible) self-prescribed over-the-counter medications

    g. wherever possible, avoid providing medical care to yourself or anyone with whom you have a close personal relationship.[6]

製薬医学は、臨床試験などの状況下で臨床的ケアに影響を及ぼす可能性があります。

医療従事者や患者に提供される情報は、使用する医薬品のベネフィットリスクプロファイルに基づいて、客観的で臨床的な意志決定を行えるものでなければなりません。

17. You must be satisfied that you have consent or other valid authority before you carry out any examination or investigation, provide treatment or involve patients or volunteers in teaching or research.[2, 8, 9]

研究には、ベネフィットリスクプロファイルが明確に確立されていない、あるいは更新されつつある実験的治療法を含む可能性があります。臨床開発プログラムの期間にベネフィットリスクプロファイルが変更された場合、参加している患者とその情報を共有するべきです。必要に応じて、研究に参加している患者からさらなる同意を得るなければなりません。

18. You must make good use of the resources available to you.[1]

あなたは、患者に関与し影響を及ぼすいかなる業務においても、その業務を有意義に実践し、完了するために、必要なリソースを確実に利用できるようにしなければなりません。

Record your work clearly, accurately and legibly

19. Documents you make (including clinical records) to formally record your work must be clear, accurate and legible. You should make records at the same time as the events you are recording or as soon as possible afterwards.

20. You must keep records that contain personal information about patients, colleagues or others securely, and in line with any data protection requirements.[10]

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21. Clinical records should include:

    a. relevant clinical findings

    b. the decisions made and actions agreed, and who is making the decisions and agreeing the actions

    c. the information given to patients

    d. any drugs prescribed or other investigation or treatment

    e. who is making the record and when.

正確な文書化は製薬医学の実務に不可欠です。GCP[xii], GVP[xiii], GLP[xiv-xv], GMP[xvi] は業務のための基本的な運用ガイドラインです。パラグラフ 19-21 の原則に記載されている他の製薬医学の実務における規制は、ICH ガイドライン [xvii] を参考にしています。

Domain 2: Safety and quality

Contribute to and comply with systems to protect patients

22. You must take part in systems of quality assurance and quality improvement to promote patient safety. This includes:

    a. taking part in regular reviews and audits of your work and that of your team, responding constructively to the outcomes, taking steps to address any problems and carrying out further training where necessary

    b. regularly reflecting on your standards of practice and the care you provide

    c. reviewing patient feedback where it is available.

製薬医学において、あなたは、他の医療関係者、規制当局、あるいは患者団体などの個人あるいは団体からのフィードバックを考慮し、必要な場合には、クオリティ（質）を改善するプログラムを実施すべきです。

23. To help keep patients safe you must:

    a. contribute to confidential inquiries

    b. contribute to adverse event recognition

    c. report adverse incidents involving medical devices that put or have the potential to put the safety of a patient, or another person, at risk

    d. report suspected adverse drug reactions

    e. respond to requests from organisations monitoring public health.

    When providing information for these purposes you should still respect patients' confidentiality.[10]

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あなたは、患者の安全性が侵されるかもしれないときには、迅速な行動をとらなければなりません。有害事象や他の安全性の懸念については、定められた手順に従い関連規制当局に報告しなければなりません。また、患者の安全に関連する当局の調査にも協力しなければなりません。

あなたは、製品の安全性のモニタリング、安全性シグナルの迅速な管理、および患者の福利に影響を及ぼす製品の品質問題のような事案の処理を実施しなければなりません。

Respond to risks to safety

24. You must promote and encourage a culture that allows all staff to raise concerns openly and safely.[1,11]

25. You must take prompt action if you think that patient safety, dignity or comfort is or may be seriously compromised.

    a. If a patient is not receiving basic care to meet their needs, you must immediately tell someone who is in a position to act straight away.

    b. If patients are at risk because of inadequate premises, equipment* or other resources, policies or systems, you should put the matter right if that is possible. You must raise your concern in line with our guidance[11] and your workplace policy.You should also make a record of the steps you have taken.

    c. If you have concerns that a colleague may not be fit to practise and may be putting patients at risk, you must ask for advice from a colleague, your defence body or us [GMC]. If you are still concerned you must report this, in line with our guidance and your workplace policy, and make a record of the steps you have taken.[11,12]

GMC の記載されている範疇を超える場においても、GMC と同等の責任ある行為がなされるべきです。

あなたは、個々の患者と公衆の健康の両者のニーズを考慮しなければなりません。この点は、患者のケアに必ずしも直接関わっていないが、患者集団の治療への反応に関してしばしば決定を下す製薬医学に従事する医師は特に関連があります。

26. You must offer help if emergencies arise in clinical settings or in the community, taking account of your own safety, your competence and the availability of other options for care.

27. Whether or not you have vulnerable† adults or children and young people as patients, you should consider their needs and welfare and offer them help if you think their rights have been abused or denied.[13,14]

あなたは、立場の弱い患者集団のニーズを配慮し、また、承認前あるいは承認後の臨床研究においてそのような集団が除外されないことを、それが適切な場合には、特別な配慮が取られなければならないことを認識しながら、保証すべきです。

Protect patients and colleagues from any risk posed by your health

28. If you know or suspect that you have a serious condition that you could pass on to patients, or if your judgement or performance could be affected by a condition or its treatment, you must consult a suitably qualified colleague.You must follow their advice about any changes to your practice they consider necessary. You must not rely on your own assessment of the risk to patients.

29. You should be immunised against common serious communicable diseases (unless otherwise contraindicated).

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30. You should be registered with a general practitioner outside your family.

あなたは、職場や居住の地域によらず、自分自身の健康に関しては、中立的な立場の医師に相談すべきです。

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* Follow the guidance in paragraph 23c (page 10) if the risk arises from an adverse incident involving a medical device.
† Some patients are likely to be more vulnerable than others because of their illness, disability or frailty or because of their current circumstances, such as bereavement or redundancy. You should treat children and young people under 18 years as vulnerable. Vulnerability can be temporary or permanent.

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Domain 3: Communication, partnership and teamwork

Communicate effectively

31. You must listen to patients, take account of their views, and respond honestly to their questions.

これは、立場が弱い、あるいは、意識のない患者をケアしている人を含みます。あなたは、患者の利益を代弁する者の意見も傾聴すべきです。

32. You must give patients* the information they want or need to know in a way they can understand. You should make sure that arrangements are made, wherever possible, to meet patients' language and communication needs.[15]

インフォームドコンセント文書、患者情報リーフレット（PIL）、患者サポート資材、ソーシャルメディアなどのコミュニケーションに当たって、あなたは、患者が必要とする情報を前もって検討するべきです。これらのコミュニケーションは、正確で、完全で、容易に理解でき、誤解を生じさせない表現を用いるべきです。

33. You must be considerate to those close to the patient and be sensitive and responsive in giving them information and support.

34. When you are on duty you must be readily accessible to patients and colleagues seeking information, advice or support.

あなたが情報、助言、またはサポートを提供する責任を担う際には、安全性の問題や医学的監視活動に容易にアクセスできなければなりません。

Work collaboratively with colleagues to maintain or improve patient care

どのような場においても、あなたは、誠実さ、すなわち、最高水準の倫理的原則と理想を推進するためにリーダーシップを発揮すべきです。

35. You must work collaboratively with colleagues, respecting their skills and contributions.[1]

36. You must treat colleagues fairly and with respect.

37. You must be aware of how your behaviour may influence others within and outside the team.

あなたは、同僚に対してとる行動に関して、最高水準を維持する職業上の責務を持ちます。製薬医学は、国際的な専門分野として実践されるため、文化や言語の違いへの配慮は、地域、国、あるいは国際的なレベルで特に重要です。

38. Patient safety may be affected if there is not enough medical cover. So you must take up any post you have formally accepted, and work your contractual notice period before leaving a job, unless the employer has reasonable time to make other arrangements.

*Patients here includes those people with the legal authority to make healthcare decisions on a patient's behalf.

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Teaching, training, supporting and assessing

39. You should be prepared to contribute to teaching and training doctors and students.

あなたは、治療の開発とその使用をサポートするために、医師およびそれ以外のスタッフのトレーニングに貢献すべきです。そうすることによって、彼らが確実に製薬医学の適切な知識を持つことの助けとなります。

40. You must make sure that all staff you manage have appropriate supervision.

41. You must be honest and objective when writing references, and when appraising or assessing the performance of colleagues, including locums and students. References must include all information relevant to your colleagues' competence, performance and conduct.[16]

42. You should be willing to take on a mentoring role for more junior doctors and other healthcare professionals.[1]

43. You must support colleagues who have problems with their performance or health. But you must put patient safety first at all times.[1]

Continuity and coordination of care

44. You must contribute to the safe transfer of patients between healthcare providers and between health and social care providers. This means you must:

    a. share all relevant information with colleagues involved in your patients' care within and outside the team, including when you hand over care responsibility as you go off duty, and when you delegate care or refer patients to other health or social care providers[5,10]

    b. check, where practical, that a named clinician or team has taken over responsibility when your role in providing a patient's care has ended. This may be particularly important for patients with impaired capacity or who are vulnerable for other reasons.

45. When you do not provide your patients' care yourself, for example when you are off duty, or you delegate the care of a patient to a colleague, you must be satisfied that the person providing care has the appropriate qualifications, skills and experience to provide safe care for the patient.[5]

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Establish and maintain partnerships with patients

患者および患者の代弁者からは、彼らからしか得られない疾病や疾患のインサイトを得ることができます。公衆衛生への関心の中で、あなたは患者の支援者と協働する義務を負います。その際、潜在的な利益相反の管理に注意を払わなければなりません。

46. You must be polite and considerate.

47. You must treat patients as individuals and respect their dignity and privacy.[12]

48. You must treat patients fairly and with respect whatever their life choices and beliefs.

49. You must work in partnership with patients, sharing with them the information they will need to make decisions about their care,[15] including:

    a. their condition, its likely progression and the options for treatment, including associated risks and uncertainties

    b. the progress of their care, and your role and responsibilities in the team

    c. who is responsible for each aspect of patient care, and how information is shared within teams and among those who will be providing their care

    d. any other information patients need if they are asked to agree to be involved in teaching or research.[9]

50. You must treat information about patients as confidential. This includes after a patient has died.[10]

あなたは、患者の個人情報を第３者と共有する場合は、適切な同意を取得し、倫理的な助言を得るなど、患者のプライバシー保護への対策を講じた上で行わなければなりません。

51. You must support patients in caring for themselves to empower them to improve and maintain their health. This may, for example, include:

    a. advising patients on the effects of their life choices and lifestyle on their health and well-being

    b. supporting patients to make lifestyle changes where appropriate.

52. You must explain to patients if you have a conscientious objection to a particular procedure. You must tell them about their right to see another doctor and make sure they have enough information to exercise that right. In providing this information you must not imply or express disapproval of the patient's lifestyle, choices or beliefs. If it is not practical for a patient to arrange to see another doctor, you must make sure that arrangements are made for another suitably qualified colleague to take over your role.[17]

Domain 4: Maintaining trust

Show respect for patients

53. You must not use your professional position to pursue a sexual or improper emotional relationship with a patient or someone close to them.[12]

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54. You must not express your personal beliefs (including political, religious and moral beliefs) to patients in ways that exploit their vulnerability or are likely to cause them distress.[17]

55. You must be open and honest with patients if things go wrong. If a patient under your care has suffered harm or distress, you should:

    a. put matters right (if that is possible)

    b. offer an apology

    c. explain fully and promptly what has happened and the likely short-term and long-term effects.

謝罪とは、ある出来事が起こったことを遺憾と感じていることの表現であり、必ずしも責任または罪を認めるわけではありません。臨床研究を行う場合、有害事象や治療の副作用を予測し、あるいは、起こりうる長期的な影響を完全に説明することができないことがよくあります。治療を開始する前にこの不確実性を説明し、根拠のない安心を与えないことが重要です。 患者が危害を受けたならば、あなたは遺憾と共感を示すべきです。

Treat patients and colleagues fairly and without discrimination

56. You must give priority to patients on the basis of their clinical need if these decisions are within your power. If inadequate resources, policies or systems prevent you from doing this, and patient safety, dignity or comfort may be seriously compromised, you must follow the guidance in paragraph 25b.

57. The investigations or treatment you provide or arrange must be based on the assessment you and your patient make of their needs and priorities, and on your clinical judgement about the likely effectiveness of the treatment options. You must not refuse or delay treatment because you believe that a patient's actions or lifestyle have contributed to their condition.

製薬医学に従事する医師は、試験依頼者を代表してまたは臨床試験担当医師として、しばしば臨床試験の実施に関わっています。その場合、その臨床試験がリサーチクエスチョンに適切に答えることができる合理的な可能性を持っていることを確信していなくはなりません。臨床試験における治療介入は正当化されなければなりません。 臨床試験担当医師として役割を担っている場合は、個々の患者を登録する時に、患者が試験を十分に完了できるかどうかの可能性を考えることが必要です。臨床試験担当医師として、あなたは患者に可能性のある転帰について助言することしかできず、また、臨床試験の期間を通じて患者の安全を考慮しなければなりません。

58. You must not deny treatment to patients because their medical condition may put you at risk. If a patient poses a risk to your health or safety, you should take all available steps to minimise the risk before providing treatment or making other suitable alternative arrangements for providing treatment.

59. You must not unfairly discriminate against patients or colleagues by allowing your personal views* to affect your professional relationships or the treatment you provide or arrange. You should challenge colleagues if their behaviour does not comply with this guidance, and follow the guidance in paragraph 25c if the behaviour amounts to abuse or denial of a patient's or colleague's rights.

* This includes your views about a patient's or colleague's lifestyle, culture or their social or economic status, as well as the characteristics protected by legislation: age, disability, gender reassignment, race, marriage and civil partnership, pregnancy and maternity, religion or belief, sex and sexual orientation.

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60. You must consider and respond to the needs of disabled patients and should make reasonable adjustments† to your practice so they can receive care to meet their needs.

61. You must respond promptly, fully and honestly to complaints and apologise when appropriate. You must not allow a patient's complaint to adversely affect the care or treatment you provide or arrange.

62. You should end a professional relationship with a patient only when the breakdown of trust between you and the patient means you cannot provide good clinical care to the patient.[18]

63. You must make sure you have adequate insurance or indemnity cover so that your patients will not be disadvantaged if they make a claim about the clinical care you have provided in the UK.

あなたは臨床試験のスポンサーが患者登録を始める前に十分な保険に加入していることを確認なければなりません。

製薬医学は国際的に実践されているので、あなたが働いているすべての地域においても十分な保険または損害賠償制度があることを確認しなければなりません。

64. If someone you have contact with in your professional role asks for your registered name and/or GMC reference number, you must give this information to them.

あなたが GMC に登録されていない場合は、あなたの地域のガイドラインに従って適切な情報を提供するべきです。

Act with honesty and integrity

Honesty

65. You must make sure that your conduct justifies your patients' trust in you and the public's trust in the profession.

66. You must always be honest about your experience, qualifications and current role.

67. You must act with honesty and integrity when designing, organising or carrying out research, and follow national research governance guidelines and our guidance.[2]

あなたが世界中のいかなる場所で研究を行う場合にも、健康上の必要性、およびこの文書で概説されている倫理および善行の原則に基づいて、試験施設を選択する必要があります。

現地の規制や低コストが臨床試験の実施に過度に影響を与えないようにする必要があります。

発展途上国における臨床試験のデザインと実施には特別な配慮を払うべきです。 これは、治療とケアの継続的提供ができきるかという倫理的および公衆衛生的な問題のためです。

† 'Reasonable adjustments' does not only mean changes to the physical environment. It can include, for example, being flexible about appointment time or length, and making arrangements for those with communication difficulties such as impaired hearing. For more information see the EHRC website (www.equalityhumanrights.com/advice-and-guidance).

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Communicating information

あなたは、すべてのコミュニケーションが現地の規制や基準、そして該当する場合にはプロモーション規範に準拠していることを確認しなければなりません。

68. You must be honest and trustworthy in all your communication with patients and colleagues. This means you must make clear the limits of your knowledge and make reasonable checks to make sure any information you give is accurate.

69. When communicating publicly, including speaking to or writing in the media, you must maintain patient confidentiality. You should remember when using social media that communications intended for friends or family may become more widely available.[10,19]

70. When advertising your services, you must make sure the information you publish is factual and can be checked, and does not exploit patients' vulnerability or lack of medical knowledge.

71. You must be honest and trustworthy when writing reports, and when completing or signing forms, reports and other documents.[16] You must make sure that any documents you write or sign are not false or misleading.

    a. You must take reasonable steps to check the information is correct.

    b. You must not deliberately leave out relevant information.

Faculty of Pharmaceutical Medicine は、情報の開示と伝達に関する以下の原則を提唱します。
あなたは、これらすべての原則を支持し推進しなければなりません。

- すべての臨床試験を適時に登録すること。
- 臨床試験の総括的な結果を全ての参加者へ迅速に伝達すること。
- 臨床試験結果の公表文書を作成する著者は、研究結果と裏付けるデータに十分に精通していること。
- 結果の要約は、臨床試験の終了後、できるだけ早く公表されなければならないこと。情報の公表日は、製品や価格の承認、あるいは臨床試験やプロジェクト全体の継続または中止によって、左右されないこと。
- 匿名化された個別患者レベルのデータの第三者への提供は、国内規制に準拠している必要があること。
- 患者、医療従事者、価格設定および償還する機関を対象とした販促資料および/または情報は、対象となる読者に対して、完全で、バランスのとれた、理解しやすいものであること。

また、あなたは、臨床試験の開示に関連するする国内法および国際法を遵守する必要があります。

Openness and legal or disciplinary proceedings

72. You must be honest and trustworthy when giving evidence to courts or tribunals.[20] You must make sure that any evidence you give or documents you write or sign are not false or misleading.

    a. You must take reasonable steps to check the information.

    b. You must not deliberately leave out relevant information.

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73. You must cooperate with formal inquiries and complaints procedures and must offer all relevant information while following the guidance in Confidentiality.

74. You must make clear the limits of your competence and knowledge when giving evidence or acting as a witness.[20]

75. You must tell us [GMC] without delay if, anywhere in the world:

    a. you have accepted a caution from the police or been criticised by an official inquiry
    b. you have been charged with or found guilty of a criminal offence
    c. another professional body has made a finding against your registration as a result of fitness to practise procedures.[21]

これは GMC に登録されている人に限定されるものです。 ただし、他の規制機関等に登録されている場合も同じ原則が適用されます。

76. If you are suspended by an organisation from a medical post, or have restrictions placed on your practice, you must, without delay, inform any other organisations you carry out medical work for and any patients you see independently.

Honesty in financial dealings

ビジネスの公正性は、製薬医学の基本原則です。

77. You must be honest in financial and commercial dealings with patients, employers, insurers and other organisations or individuals.[22]

78. You must not allow any interests you have to affect the way you prescribe for, treat, refer or commission services for patients.

79. If you are faced with a conflict of interest, you must be open about the conflict, declaring your interest formally, and you should be prepared to exclude yourself from decision making.

80. You must not ask for or accept – from patients, colleagues or others – any inducement, gift or hospitality that may affect or be seen to affect the way you prescribe for, treat or refer patients or commission services for patients. You must not offer these inducements.

スポンサーシップ、贈答品、接遇、および医療に関連する助成金およびサービスの提供に関して、あなたは関連する国内外の関連法、規制およびガイドラインの範囲内で活動しなければなりません。

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日本語訳担当：中江文、浅尾啓子*、西馬信一、内田一郎（日本製薬医学会教育部会）

*アステラスアムジェンバイオファーマ KK

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Faculty of
Pharmaceutical Medicine

3rd Floor, 30 Furnival Street
London EC4A 1JQ
United Kingdom

Company No: 6870644
Registered Charity No: 1130573
www.fpm.org.uk
Email: fpm@fpm.org.uk