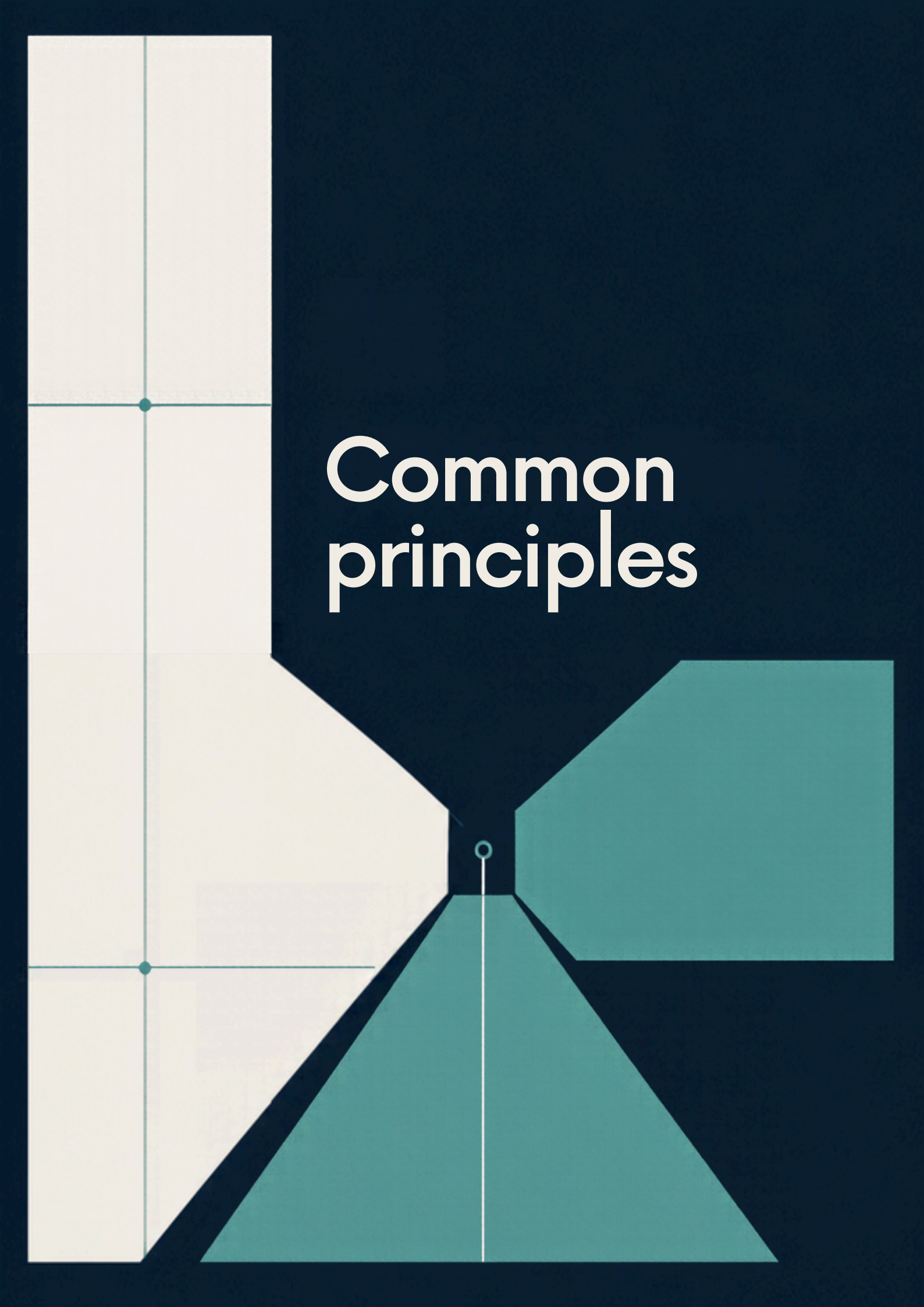


An abstract geometric composition on a dark navy blue background. On the left, a vertical cream-colored bar is divided into four equal segments by thin teal lines. Two teal dots are positioned at the intersections of these lines. To the right of this bar, a large teal triangle points upwards, its apex meeting a small teal circle. A thin white vertical line descends from this circle. To the right of the triangle's apex is a teal pentagon. The overall design is minimalist and architectural.

Common principles

1 General principles for collaboration

This guide helps patient organisations and pharmaceutical companies understand each other's responsibilities and establish collaborations that are useful, respectful and practical. It focuses on human prescription medicines and collaboration across the medicine lifecycle, including awareness, information, research, development, safety, regulatory review and access. Individual patients, advocates and carers are included where they participate in these relationships.

The scope is the EU core and 26 country chapters: UK, France, Germany, Netherlands, Sweden, Switzerland, Poland, Italy, Spain, USA, Canada, Brazil, Mexico, China, Japan, Singapore, India, South Korea, Australia, New Zealand, Saudi Arabia, Belgium, South Africa, Türkiye, Argentina and Taiwan. The general principles provide a shared planning approach; national chapters identify differences that may change a project decision.

1.1 How to use these principles

These principles support discussion before a collaboration begins and help resolve questions during delivery. They are recommendations unless a specific source establishes a requirement. A practical recommendation must be considered alongside the applicable local framework, and should not be described as a universal legal obligation.

International industry standards provide a useful starting point. The IFPMA Code and supplementary guidance address company–patient organisation relationships, but their applicability must be established for the company and activity. They are industry standards rather than legislation and should be read alongside national requirements (International Federation of Pharmaceutical Manufacturers and Associations [IFPMA], 2019, 2020).

Source	How to understand it
Law or regulation	Establish the jurisdiction, organisations, individuals and activities covered.
Industry code	Check whether the company or activity falls within scope and how compliance is enforced.
Authority requirement or guidance	Distinguish participation conditions, procedural requirements and recommendations.
Organisation policy	Identify whose policy applies, why it exists and who can discuss alternatives.
Recommended practice	Consider how the recommendation supports a fair and workable collaboration.

If the guide does not cover an activity, check what requirements apply before proceeding. If a company says something is not allowed, the organisation should be able to ask whether the restriction comes from law, a code, an authority or company policy. The company should explain the reason clearly so both partners can explore suitable options.

1.2 Start with a clear patient benefit

Every collaboration should begin with a discussion about what it is intended to achieve and why that matters to patients. The purpose might be better information, understanding unmet needs, accessible research participation, treatment-experience evidence or an improved service. Both partners should be able to explain how the activity is expected to contribute to the intended benefit.

Patient involvement can contribute from early development through regulatory review to monitoring and safe use. Its form should reflect the decisions being made and the knowledge needed. CIOMS describes the value of systematic

involvement while recognising that recommendations need adaptation to organisational and national circumstances (Council for International Organizations of Medical Sciences [CIOMS], 2022).

Involve the organisation while important decisions remain open. Explain what participants can influence, what has already been decided and what limitations apply. Commenting on a completed leaflet offers a different opportunity from helping identify information needs before drafting starts. Agree realistic indicators of success without promising a clinical benefit or a company decision that the project cannot guarantee.

1.3 Respect each partner's responsibilities

Patient organisations may contribute lived experience, community relationships, knowledge of service gaps and understanding of participation barriers. Companies may contribute scientific expertise, resources, funding and development experience. Collaboration should make room for these contributions without assuming either partner understands the other's arrangements.

A volunteer-led organisation may need board or member consultation. A company owner may need medical, legal, compliance, privacy, safety, procurement or finance review. Explain these arrangements early, identify decision-makers and distinguish initial interest from an authorised commitment. Where approval is outstanding, say so before the other partner undertakes substantial work.

1.4 Preserve independence and freedom of expression

An organisation should retain control of its mission, priorities and positions. IFPMA requires respect for independence, clarity about company involvement and, where its Code applies, prohibits a company from requiring sole-funder status for an organisation or its programmes (IFPMA, 2019, arts. 11.1–11.2).

Independence must be reflected in practical arrangements. Discuss who decides priorities, how disagreements are handled and whether findings may be communicated when they differ from company expectations. Distinguish company-commissioned outputs from independent organisational publications and define the purpose and limits of company review.

Confidentiality may protect unpublished research, commercially sensitive information or personal information. Explain what is protected, why, who may receive it and how long the obligation lasts. Address necessary disclosures to governing bodies, advisers and authorities. Agree use of names, quotations and logos; participation in one activity should not automatically imply endorsement of the company, a medicine or a wider position.

1.5 Be clear about whose views are being shared

Individual experience, an organisational position and consultation findings are different contributions. Agree which is sought before recruitment or preparation. One person should not be expected to speak for everyone with a condition. Differences in age, disease stage, disability, treatment, income, location and access can all affect experience, while an uncommon account may reveal an overlooked problem.

If a collective position is needed, discuss how it will be developed. Consultation may require accessible questions, outreach, analysis and organisational approval. Recognise this work in the scope, timetable and budget. When reporting, describe who contributed, how views were gathered and whose experiences may be missing. Avoid presenting a small invited discussion as evidence of what all patients want.

1.6 Check governance and authority to agree

Identify the legal entity and the people authorised to commit it. Check governing documents, purposes, industry-relationship policies and relevant funding conditions. Do not assume charitable status from public-benefit work: associations, foundations, charities, companies and informal networks can have different arrangements.

If a network cannot contract directly, consider an appropriate host or other lawful arrangement. Explain who receives funds, oversees delivery and accepts responsibility. The company should make equivalent checks about its own entity and approvals. A spokesperson's willingness or a project owner's enthusiasm does not establish authorised agreement.

1.7 Design participation around capacity

Participation includes preparation, consultation, reviewing documents, arranging support, travel and follow-up, not just attending a meeting. Discuss the whole workload before fixing deadlines. Ask what would help, such as interpretation, accessible documents, shorter meetings, breaks, flexible scheduling or a support person. Do not require unnecessary health disclosure.

Assess the particular organisation and activity rather than infer capacity from country, size or legal status. A small group may offer considerable expertise but little administrative time. Both partners should be able to raise concerns. Added meetings, consultation or outputs should prompt discussion of time, cost and participation before scope changes are accepted.

1.8 Explain funding and payment clearly

Describe the support and associated obligations before anyone commits. Donations, grants, sponsorship, services, expenses and in-kind support may be governed differently. Their substance and applicable framework determine classification, rather than the label alone.

Agree the payee, covered activities and costs, exclusions, invoices, payment dates and arrangements for delay or cancellation. Where permitted, recognise preparation and follow-up. Discuss advances or direct booking if participants cannot meet upfront costs. Explain individual fees early enough for people to consider their circumstances and seek advice.

The guide sets no universal remuneration rate, funding-dependence percentage, hospitality allowance or payment timetable. Any numerical requirement must identify its source, scope and effective date. Attribute company-policy figures to the company.

1.9 Make administration proportionate

The company should explain the information needed, its purpose and what must be completed before work begins. Provide one coordinated request and reuse or update current records where possible. Supply banking and other sensitive details through a suitable secure route.

Where a requested document does not exist, discuss alternative evidence meeting the underlying need. Give the organisation a named coordinating contact. Before volunteers prepare materials or consult members, explain approvals still outstanding, whether preparation may begin, whether it will be paid and what happens if the project stops.

1.10 Use clear written agreements

An agreement should be understandable to the people delivering the work and proportionate to the activity. Where IFPMA applies, financial or in-kind support requires written documentation describing its nature, purpose and funding (IFPMA, 2019, art. 11.3).

Topic	What to explain
Purpose and scope	Intended outcomes, included activities and deliverables.
Responsibilities	Who performs, reviews and approves the work.

Topic	What to explain
Funding and payment	Amounts, costs, timing and cancellation terms.
Independence and communications	Editorial control, acknowledgement and names or logos.
Information and materials	Privacy, confidentiality, ownership and permitted uses.
Safety and research	Assessment, training, reporting and approvals where applicable.
Changes and closure	How to amend, end and evaluate the collaboration.

Allow time for questions before signing. If standard wording does not fit, explain the review route. The organisation should identify terms conflicting with its governance, existing commitments or ability to deliver.

1.11 Be open about support and interests

Agree how financial and non-financial involvement will be acknowledged and who makes required disclosures. EFPIA identifies disclosure of financial relationships with patient organisations as a Code requirement, but this European framework should not be assumed to establish every market's rules (European Federation of Pharmaceutical Industries and Associations [EFPIA], n.d.).

A declaration informs an assessment; it does not necessarily resolve an interest or establish eligibility for another role. Check the specific authority and participation requirements before accepting work where possible. EMA illustrates an authority-specific framework that can restrict expert participation according to interests and activity; neither universal exclusion nor automatic irrelevance should be assumed (European Medicines Agency [EMA], n.d.).

1.12 Plan communications around purpose and audience

Before developing materials, agree their purpose, content, audience, distribution and the company's role. Calling an activity educational or disease awareness does not settle classification. Consider the overall message and context, including direct or indirect attention to a medicine.

Detailed disease knowledge and patient-organisation membership do not automatically confer healthcare-professional status. Advertising rules differ across markets, so apply the local framework. Explain restrictions and consider alternative content or formats. Agree reuse: a meeting presentation may need further assessment before online publication, recording or social-media distribution.

For personal stories, explain wording, images, audience and channels before seeking permission. Discuss review by the contributor and practical limits on removal after publication.

1.13 Protect information and individual choice

Map what personal information is needed, why, who receives it, access controls, storage, retention and international transfers. Consider anonymous findings or a summary instead of identifiable responses. Where possible, the organisation can circulate invitations and let individuals contact the provider without disclosing its membership list.

Establish the applicable privacy framework. Where GDPR applies, an Article 6 basis and an Article 9 condition are needed for health information. A funding agreement does not itself authorise disclosure of members' health information (European Parliament & Council of the European Union, 2016, arts. 6, 9).

Explain participation, recording and publication as distinct decisions. Removing a name may leave someone identifiable from diagnosis, location, treatment or family circumstances. Review the combined details before calling information anonymous.

1.14 Agree safety and research responsibilities

Before recruitment or collection, obtain the appropriate assessment of safety arrangements. If the organisation has a reporting role, provide instructions, proportionate training, a secure route, timelines and a contact for uncertainty. Explain possible follow-up and avoid confidentiality promises inconsistent with the arrangements.

Document whether the activity is advice, market research, health research, a clinical trial or another project, and identify required approvals. The title alone does not establish classification. The guide sets no universal reporting deadline and does not assume every funded group becomes a company service provider. Reassess changes to questions, data, participants or uses.

1.15 Address cross-border activity

Identify where organisations and participants are based, where work occurs, where materials are accessible and where money and information move. Assess organisational authority, fundraising, payments, communications, research and transfers for the actual arrangement.

The company should coordinate its assessment and explain practical consequences. The organisation should identify restrictions from governance, funding or local obligations. Governing-law wording and an agreement used elsewhere do not resolve every cross-border question.

1.16 Share responsibility for delivery and learning

Name contacts, escalation routes and methods for discussing progress, concerns and changes. Explain approval stages and realistic estimates, including the organisation's consultation timetable. If delays occur, discuss workload and cost before setting new deadlines.

Participants should know how to raise concerns, withdraw or explain changing availability. At closure, review patient benefit, participation quality and administrative burden. Provide feedback on how contributions were used and why some suggestions could not be adopted. Complete payment, disclosure, records and information-retention actions.