

Regulatory Rapporteur style guide

Last updated: 4 December 2024

Note: The European Commission has a useful online publication that comprehensively covers uniformity relating to stylistic rules and conventions which must be used by all institutions, bodies and agencies of the EU for document production. It can be found online at: <https://style-guide.europa.eu/en/home>

General

- Keep **paragraphs** short (fewer than ten lines).
- Keep **sentences** as short as possible. If a sentence is over twenty words, consider splitting it. Thirty is the absolute maximum.
- Always use **British English** spelling unless giving the name of something from the US, e.g. a US regulation/law/programme/agency/organisation when original US spelling should be used, e.g. FDA Modernization Act, US Rare Pediatric Disease Program. This means foetus, oestrogen, leukaemia, ising, -isation.
- Keep **capitalisation** to a minimum (while remaining accurate). Ditto commas.
- Never allow **double spaces**, use Ctrl-F to replace with single space.
- To avoid awkward breaks across two lines, e.g. between Phase I; Regulation No; Article 1; Dr Smith; use **non-break space – CTRL + SHIFT + Spacebar**.
- Try to avoid **dashed clauses**; use brackets if necessary but try and rewrite the sentence to avoid the need for either.
- **URLs** are not underlined and only have a full stop at the end when they are at the end of a sentence.
- **Lists** in body text should be in alphabetical order unless there is an overriding reason (which should be stated). For example, lists of countries or organisations/people (by surname) should be in alphabetical order. This is to ensure that there is no implied order (of importance or otherwise) beyond an accepted objective standard.

Abbreviations

- Things that can be abbreviated should be spelled out the first time with the abbreviation in round brackets and thereafter referred to by the abbreviation only, e.g. The Massachusetts Institute of Technology (**MIT**) introduced its first speaker, MIT graduate Joe Blogs. Only use 'hereafter' when the author is introducing a new abbreviation which they invented or which is very uncommon, even to those with specialist knowledge.
- Do not spell out: EU, US or UK. However, the following *should* be spelled out on first instance: European Medicines Agency (EMA), US Food and Drug Administration (FDA), World Health Organization (WHO), National Institute for Health and Care Excellence (NICE) and all other organisations.
- Note: The FDA (not FDA); The WHO (not WHO)

- The first time you use an abbreviation, it should be full out followed by the abbreviation in brackets. Should the full out term be in title case or sentence case? This depends according to the [abbreviations glossary](#).
- **e.g./i.e.** in this format, with each letter followed by a stop and without commas, colons, or any other punctuation.
exempli gratia: ‘For the sake of example’.
id est: ‘That is’ / ‘in other words’.
- No full stops in abbreviations, or between initials: **EU, US, ICH, NICE**.
- Kilogram/s, kilojoule/s, kilometre/s, kilowatt/s: Abbreviate as **kg, kJ, km, kW**.
- **Research and development**: Spell out the first time with abbreviation, ‘Steven helped with research and development (**R&D**).’ Thereafter use **R&D**.
- **Rx** is the abbreviation for prescription; capital R.
- **SmPC not SPC**: adopted as the correct terminology by EMA working groups. [Note: SPC also stands for Supplementary Protection Certificate (EU) and Special Precautions and Contraindications.]
- **Subject matter expert** or SME.

Capitalisation

- **Proper names** are capped.
- **Common nouns** such as party, river or street are capped only when they are part of a proper name e.g. the Republican Party.
- **Job designations/titles**: These should be initial upper case when referring to someone’s specific job title (e.g. Prime Minister, US Secretary of State, Editor of *Regulatory Rapporteur*) but lower case when talking about roles in general (e.g. Lots of editors work here.)
- **British government departments of state, when using the proper name**: All initial caps
- e.g. Home Office, Foreign Office, Ministry of Defence (MoD on second mention). But when not the proper name, use lower case, e.g. state department, health ministry.
- **Universities and colleges of further and higher education**: caps for institution and departments [in body copy] (e.g. Cambridge University Department of Medicine, Oregon State University, Free University of Berlin, University of Queensland School of Medicine).
- **Common RA industry terms**: Always lower case, followed by abbreviation at first mention (e.g. investigational medicinal product (IMP), investigational medicinal product dossier (IMPD)).
- **Awards, prizes, medals** are generally title case (e.g. Nobel Peace Prize, Fields Medal).
- **Brand names**: Initial caps followed by generic name in brackets (e.g.: Avastin (bevacizumab)). Do not use registered trademark® or ™ symbols following the brand names. Typically use European brand name vs US (e.g. Glivec vs Gleevec), unless it is most known by its US name.
- **Taxonomic names** (e.g. E coli) should be italicised in copy but not in headlines or standfirsts. Use non-break space to keep together.
- **Guidelines** should be initial caps if referring to a specific guideline but lower case if referring to guidelines in general.
- **Headlines/crossheads/contents titles**: Use initial cap of first word only and another initial cap for word following a colon.
- **Keywords**: Use initial cap of each key word or phrase, semi-colon between each, full stop on final keyword (e.g. Biologicals; Antibody drugs; Carcinogenicity; Cellular proliferation assays).
- **Geographical areas** are lower case for regions: the north, the south of England, the south-west, north-east England; the same applies to geopolitical areas: the west, western Europe, far east, south-east Asia, central America etc. However, use initial caps when part of the name of a county (West

Sussex, East Riding) or province (East Java, North Sulawesi, etc). Note the following: West Country, Middle East, Latin America, North America.

- **Act/act:** Use initial caps when using full name, e.g. Food and Drug Administration Amendments Act (FDAAA) and upper case 'A' when referring to a specific act (e.g. 'the Act'); use lower case when speaking in more general terms, e.g. 'we need a revised freedom of information act'.
- **government** is lower case.
- **agency** is lower case, including, for example, 'the Greek agency, EOF', unless talking about a specific agency with the word 'agency' in its title (e.g. on second mention of the European Medicines Agency, you could say 'the Agency').
- **Regulation(s):** Initial caps if referring to a specific regulation; lower case if referring to regulations in general.
- **The following are lowercase:**
 - advanced therapy medicinal products (ATMPs)
 - advanced therapies is lower case, but Advanced Therapy Regulation
 - competent authority(ies): lower case unless talking about a specific CA (e.g. the UK Competent Authority)
 - decentralised procedure (DCP)
 - euro (l/c)
 - mutual recognition procedure (MRP)
 - notified body (NB) is lower case unless talking about a specific notified body, e.g. the UK Notified Body
 - primary care trusts
 - regulatory affairs
 - regulatory affairs professional
 - regulatory agency
 - scientific advice
 - user testing
 - website
- **The following are initial caps:**
 - Betaferon is a TM; the generic term for the drug is lower-case initial letter, interferon-beta 1b
 - Commission, as in European Commission: initial upper case 'C' when using 'the Commission noted...' (Always write 'European Commission' at first mention)
 - FemTech is a case exception
 - Quality by Design (QbD)
 - Regulatory Affairs Professionals Society (RAPS)
 - Regulatory Rapporteur (NB not the regulatory rapporteur)

Commas

- In general, **avoid excessive commas**. Do not use the Oxford comma, except when it would be confusing not to.
- Note the **distinction** between these two:
'The associate editor, John Brown, always follows house style guides' – correct (commas) if there is only one associate editor.
'The associate editor John Brown always follows house style guides' – correct (no commas) if there is more than one associate editor.

- **Introductory phrases** such as ‘However’, ‘Nonetheless’, ‘Instead’, should all be followed by a comma.

Countries and regions

- **UK** (not Great Britain, Britain, GB).
- **US** (not USA, America).
- **the Netherlands** (not The Netherlands).
Holland: do not use when you mean the Netherlands (of which it is a region)
- **Colombia vs Columbia**: South American country of Colombia vs District of Columbia (Washington DC) and Columbia University (New York)
- **Ukraine** (not ‘the Ukraine’); adjective Ukrainian
- **Oceania**, a preferable term to Australasia, (see Oceania for further definition)

Currency, numbers, symbols

- Use ‘%’ in body text rather than writing out ‘per cent’ (e.g. $\pm 5\%$), stability conditions (e.g. 25°C/65%RH), confidence intervals (e.g. 95% confidence interval), or strength of a product (e.g. Product X 0.5% nasal spray) and use % symbol in tables.
- Do not use the ampersand (&) unless special case. Use in company names/conference titles/publication names only when the originator does.
- Use **accents** on French, German, Spanish and Irish Gaelic words (but not anglicised French words such as cafe, unless the word may be misread, e.g. use exposé, résumé).
- **Numbers one to ten are written out**; 11 upwards in numerals. Except:
 - With abbreviations: 5mg, £4.50
 - In titles: 2nd annual meeting of...
 - In dates: 1 January 2018
 - Numbers over a thousand have a comma: 5,000.
- **Millions, billions** – use the word, e.g. ‘Three million sufferers worldwide...’ unless currency (or similar) in which case use abbreviations (£10m).
- **‘One in six’ is plural** (one in six ARE covid sufferers).
- **Abbreviate dollars** like this: US\$50 (US dollars); A\$50 (Australian dollars); HK\$50 (Hong Kong dollars); no space between currency signs and figures).
- **Convert all UK sterling amounts to US\$** in brackets at first mention, e.g. £50,000 (US\$73,700) – add date & rate to currency conversion).
- **Use symbols, not words**, when depicting sums of money, for: £, \$, €, ¥. [Note: ¥ is the currency symbol used for the Japanese yen (JPY) and the Chinese yuan/renminbi (CNY). NB: The actual symbol for the yuan/renminbi is ¥.]
- When the whole word is used, it is **l/c**: euro, pound, sterling, yen, dong, etc.
- **Abbreviations**: Millions = £10m | Billions = £10bn.

Dates

- **Days of the week** are not normally used in dates.
- The **day number** always comes before the month: 1 January 2018.

- 1980s, 1990s (**no apostrophe, and no short form**, i.e. 90's).
- 21st **century**; fourth century BC; AD2006 but 1000BC.
- **Do not use 'st', 'nd', 'rd' or 'th'**.

Headings

- In general, headings, subheads and crossheads should be **aligned left**, use **initial cap** for the first word but otherwise in **sentence case**, and distinguished from body text by use of **bold**.
- Keep structure simple but if there is need for a **colon**, the following word should have an initial cap.
- Use **abbreviations** where appropriate, again to keep heading simple (and short), noting that first instances of these should be in full in body text.

Hyphens

- There are **three lengths** of what can be called dashes or hyphens:
 - *hyphen* (-),
 - *en-dash* (–) typed as Alt 0150 or Alt 8211 or Ctrl + minus sign (*from numbers keypad*)
 - *em-dash* (—) typed as Alt 0151 or Ctrl + Alt + minus sign (*from numbers keypad*)
In InDesign, it's ALT + hyphen.
- Note: en-dash so called because it's the width of an 'n'; m-dash is the width of an 'm'.
- **en-dash** is used to represent the word 'to', e.g. 12–14 January; benefit–risk ratio. Note no spaces between the figures/words. To create an en-dash in Word, use CTRL + minus sign on number pad.
- **em-dash** is not house style. Convert any em-dashes to en-dashes.
- In general, avoid hyphenating if it's possible to have a singular word i.e. cooperate, nonclinical, website, laptop and email, thinktank, clearcut, longlist, shortlist. Hyphenate only if followed by vowel, not if consonant e.g. re-examine but rerun. Exceptions are coordinate/coordinator; cooperate/cooperative.
- Prefixes such as macro, mega, micro, mini, multi, over, super and under rarely need hyphens. Hyphens should, however, be used to form short compound adjectives, e.g. two-tier health service, ten-year patent, 19th-century physician, etc.
- Do not use hyphens after adverbs ending in -ly, e.g. politically naive, wholly owned, but when an adverb is also an adjective (e.g. hard), the hyphen is required to avoid ambiguity – it's not a hard, pressed scientist, but a hard-pressed one; an ill-prepared report, rather than an ill, prepared one.
- Use hyphens with short and common adverbs: much-needed treatment, well-established principle (note though that in the construction 'the principle is well established' there is no need to hyphenate). Do not hyphenate 'side effect'.
- Do not hyphenate crossover, antidepressant, gastrointestinal, lifecycle, dataset, multicentre, heart rate, healthcare, website, multisite, multidisciplinary.
- Do hyphenate electronic shortening only when it is unclear, e.g. eLearning, eCTD, but e-commerce
- Do hyphenate post-approval, hold-up, post-marketing, decision-making, sub-anything, real-world, non-compliance, non-clinical, long-term (in e.g. long-term commitment; but NOT in, e.g. in the long term)
- When referring to ranges, use en-dash (i.e. CTRL + minus sign on number pad), for instance, 30–40.
- No hyphen in:
 - Anticancers
 - Antidepressants
 - cooperate, cooperation, cooperative

- coordinate
- drug companies, and drugmakers is all one word
- eCTD (no hyphen)
- email
- endpoint
- lifecycle
- multicentre
- multisite
- user testing

Images and figures

- Must be referred to in the text at appropriate point, e.g. (see **Figure 1**) – and in the right order.
- Make the reference bold; e.g. ‘...as you can see from the data presented in **Table 1**, below.’
- When referring to a **sidebar or box of text**, write ‘(see **Box 1**)’.
- Use a **colon after figure number**, e.g. **Figure 1: XXXXXXXXXXXXX**; title in lower case (after first initial) except where it contains words that are capitalised anyway; no full stop.
- Check for **coherence in a table** (for example, that numbers in columns add up to the total shown) and for consistency with references to the Figures in the text.
- Ensure each **axis is labelled** to indicate what the figures represent (e.g.: ‘Number of trials’, ‘Number of patients’).
- Ensure **appropriate choice of chart** (e.g. out of 100 = pie chart not a bar chart, etc).

Italics

- Use italics for **journals/monographs/books titles**. No quotation marks. Cap up each word. Italicise names of all publications.
- Do not use italics for **Latin words and phrases**, e.g. et al, ad hoc, in vitro, in vivo, in silico (use non-break space to keep words together).
- Use italics for **bacterial and viral taxa** at the level of family and below. All bacterial and many viral genes are also italicised.

Names

- **Author listings**
Author boxes – list all authors
Author box listing details: Author full name (no title); job title; organisation, county/state; country. (No web address.)
Authors in references: name only three before ‘et al’ as a general rule.
- **Author names**
No ‘Mr/Mrs/Ms/Miss/esqu’ titles, but we should include titles where relevant to their credibility so DO include: ‘Dr’, ‘Professor’, ‘OBE’, ‘Lord’, etc. both on Contents Page and in Author boxes.
- **In reporting:** Prominent figures can just be named in articles, with their function at second mention: ‘Thomas Lönnngren said yesterday...’ (first mention); ‘the Agency’s Executive Director added...’ (subsequent mentions).
Where it is thought necessary to explain who someone is, write: ‘Jan Lundberg, AstraZeneca’s

Executive Vice-President, said’, or: ‘AstraZeneca’s Executive Vice-President, Discovery Research, Jan Lundberg, said’.

In such cases, the commas around the name indicate there is only one person in the position, so write ‘the Tory leader, Rishi Sunak, said’ (only one person in the job), but ‘the former Tory leader David Cameron said’ (there have been many).

Use a person’s first and last name the first time he or she is mentioned. On second reference, use only last name with no title. Do not use courtesy titles such as Mr, Mrs, Miss or Ms – unless they are part of a direct quotation or are needed to differentiate between people who have the same last name.

Numerations, bullets, lists

Use bulleted lists to:

- Help users skim information
- Group related information
- Help users understand how items relate to each other

List items should be **short** (not more than 30 words). If each item is longer, use subheadings to display text rather than a list.

Make sure lists do not follow from **open sentences** (e.g. use this as a list opener: ‘This includes the following:’, rather than ‘This includes:’).

Lists should start with capital letters but have **no punctuation at the end**, even at the end of the last item. For example:

- First bullet point
- Second bullet point
- Final bullet point

For **non-sequential lists**, use a bullet list. If there is a need for a sublist, use full bullet and transparent bullet: For example:

- Full bullet
 - Transparent bullet

If the list has **sequential items**, use a number list, with full sentences, initial caps and no punctuation at the end. For example:

1. First step
2. Second step

Quotations

- **People we interview** are allowed to speak in their own, not necessarily *Regulatory Rapporteur’s*, style, but be sensitive: do not, for example, expose someone to ridicule for dialect or grammatical errors

- **ellipses** [...] use spaces before and after ellipses, and three dots (with no spaces between them), when parts of a direct speech are cut, e.g. ‘She told me she didn’t want to enrol on the trial ... her main concern was leaving her children.’
- **quote boxes/pull quotes**
Aligned left in a right-hand column and right in a left-hand column. Centred in a central column. No full stop. Italicised. No more than six lines.
Use opening and closing quote marks only if the extract is direct speech in the body text, or if it is an opinion piece.

Quotation marks

- Use **single quotation marks** for anything which might be a quotation, i.e. something that a person or organisation said or wrote.
- **Comma** before a quote (or **colon** if lengthy quote); make first word an initial cap, e.g. Dr Brown said, ‘In hypertension, the goal is to reduce mortality,’ although she agreed there were other useful endpoints.
- With a full quote, all punctuation is placed **inside the quote marks**: ‘In hypertension, the goal is to reduce mortality.’
- For part of a quote, punctuation is placed **outside the quote marks**: The patient said she was ‘in moderate pain’ following the operation.
- If most of the sentence is a quote, but perhaps starts with an attribution, put punctuation **inside end quote**, e.g. The research team’s director said, ‘In hypertension, the goal is to reduce mortality.’
- For a **quote within a quote**, use “double” quotation marks.
- Use single quotes around **article titles** in body text and in references.

References

In general, references should follow **Harvard style**. This style guide covers Harvard referencing for a range of formats: <https://www.librarydevelopment.group.shef.ac.uk/referencing/harvard.html>

However, for RegRap we amend the Harvard style to be **more consistent** – i.e. only journals and publishers are italicised, titles are always in single quotes, years come after the author and before the title, (Available at:) is always in round brackets, never square, full stops in between pieces of information.

So, the **standard style for all references** (articles, books, guidelines, reports, etc.) is:

Author Surname INITIAL(S) or Corporate Author (Year of publication) ‘Title of reference’. *Journal/Publisher*. Volume/version (if applicable) Paper number (if applicable) pp.[page range] (if applicable). Available at: URL (Accessed: date).

- URLs in references are **not hyperlinks**, not blue (black), and not underlined.
- If there are **multiple authors** you can list them like this: Bloggs J, Smith M, Roberts JP
- **Accessed dates** like this: 1 January 2024
- Use **p76 for page 76** or **pp.20-30** to reference the range of pages from page 20 to page 30.
- There are **no commas** in references except between authors.
- **For a journal article with a DOI** you don't need to include ‘Available at’ or ‘(Accessed: date)’ in the reference as a DOI is a stable identifier and will not change, whereas a URL may change or be deleted so the extra information is needed to clarify where and when you found the article.

- There are **no commas** in references except between authors.
- Always write **DOI in lower case** letters in your references, e.g. doi.
- **Never put a full stop after a DOI or URL** as it may be assumed that it is part of the DOI or URL and prevent it from working.
- Enclose the **title of the article** in single quotation marks.
- **Capitalise the first letter of each of the main words of the journal title**, but not the linking words such as 'and', 'for', 'of' or 'the'.
- **Reference numbers in the body text** are placed outside the punctuation (preferably at the end of the sentence), in bold red and with no space. **1** in edits, which is converted to a dynamic superscript reference in Webvision.
- NB: when using page ranges, **use an en dash (–) in between the numbers**, not a hyphen e.g. pp.4–8.

Special cases:

- **For websites and databases in general** (as opposed to specific articles on websites), just use: domain 'Title of website or database' *Library/Source* (if applicable). Available at: URL (Accessed: date).
e.g. nih.gov 'GenBank' *National Library of Medicine*. Available at: <https://www.ncbi.nlm.nih.gov/genbank/> (Accessed: 23 August 2024).
- **For articles with a DOI**, replace the URL and accessed with the DOI, like this:
Author Surname INITIAL(S) or Corporate Author (Year of publication) 'Title of reference'.
Journal/Publisher. Volume/version (if applicable) Paper number (if applicable) pp.[page range] (if applicable). doi: number
e.g. Bruetschy C (2019) 'The EU regulatory framework on genetically modified organisms (GMOs)'. *Transgenic Research*. Aug;28(Suppl 2) pp.169-174. doi: 10.1007/s11248-019-00149-y
- **Web pages (specific)**, use:
domain. Group or Corporate author (Year site was published/last updated) 'Title of web page'. Available at: URL (Accessed: date).
e.g. World Health Organization (2023) 'Antimicrobial resistance'. Available at: <https://www.who.int/news-room/fact-sheets/detail/antimicrobial-resistance> (Accessed 12 May 2024).
- **For offline references, such as books:**
Author Surname INITIAL(S) or Corporate Author (Year of publication) 'Title of reference'.
Journal/Publisher. page number or page range.
e.g. Kay A (2017) 'This is Going to Hurt: Secret Diaries of a Junior Doctor'. *Picador*. p28.
- **For specific chapters in offline references, such as books:**
Author Surname INITIAL(S) or Corporate Author 'Title of reference' in Editor Surname INITIAL(S) (Year) 'Title of book'. *Journal/Publisher*. pp.[page range].
e.g. Lin AYM, Lomas JD 'The Enigma of Mind: A Theory of Evolution and Conscious Experience' in Ward EJ and Reuvers R (2022) 'Enigmas'. *Cambridge University Press*. pp.179–228.

Here are some examples of things we change for *RegRap* from the Sheffield Harvard style guide:

1. **For Reports**, do not use:
Author Surname INITIAL(S) or Corporate Author (Year of publication) *Title of report*. Paper number (if applicable). Available at: URL (Accessed: date).
Use instead:
Author Surname INITIAL(S) or Corporate Author (Year of publication) 'Title of report'.
Journal/Publication. Paper number (if applicable). Available at: URL (Accessed: date).

2. **For Government Publication – Act of Parliaments**, do not use:

Title of Act including year and chapter number. Available at: URL (Accessed: date).

Use instead:

Country (Year effected) 'Title of Act'. Available at: URL (Accessed: date).

3. **For Web pages, do not use:**

Group or Corporate author (Year site was published/last updated) *Title of web page*. Available at: URL (Accessed: date).

Use instead:

Group or Corporate author (Year site was published/last updated) 'Title of web page'. Available at: URL (Accessed: date).

Tables

- Use initial cap only (and then sentence case) **for column/row headers**
- Try to **avoid using bullet points** in tables unless absolutely necessary
- **Use numbers if necessary** to show sequential order (and not lettering/roman numerals)

Wording preferences

- amid, not amidst
- among, not amongst
- before or in advance of, not ahead of, not prior to
- around, not about (around 50 million, not about 50 million)
- big, large, not massive, giant, mammoth
- chair or chairperson not chairman or chairwoman
- low-, middle- and high-income countries, not 'the third world', 'developing countries', 'the West'
- disk, not disc
- first, second, third, not rather than firstly, secondly, thirdly
- more than, not over
- said, not commented
- nonclinical, not preclinical
- often, not frequently
- on, not upon
- past, not last (as in, in the past 10 years not in the last 10 years)
- while, not whilst

Avoid:

approach, usually redundant. Compare 'a proactive approach to pharmacovigilance' to 'proactive pharmacovigilance'

paradigm, paradigm shift. Where appropriate, try using: new strategy, new programme, new framework, 'change in strategy', etc.

Spelling, grammar and helpful facts

Things you may already know but it's helpful to have reminders.

A-Z

A

'a' or 'an' before acronyms

Use the article a before an acronym or abbreviation that begins with a consonant sound (*phonetically*), and an before one that begins with a vowel sound (*phonetically*). Whether to use a or an depends not on how the abbreviation is written, but how it is pronounced or read aloud. Examples:

- a NATO member but **an** NBA player
Even though both abbreviations begin with 'N,' NATO (pronounced 'NAY-toh') begins with a consonant sound, while NBA (pronounced 'en-bee-AY') begins with a vowel sound.
- a NICU doctor but **an** NFT
- a SARS vaccine but **an** SOS
- a FICA contribution but **an** FBI agent
- a HEPA filter but **an** HTML page
- a LAN password but **an** LED screen
- a MoMA curator but **an** MBA graduate
- **an** ATM but a UFO
- **an** EST clock but a UTC or a GMT clock

adverbs

No hyphens after adverbs ending in -ly, e.g. a hotly disputed decision, a constantly evolving journal, genetically modified food, etc; but hyphens are needed with short and common adverbs, e.g. ill-prepared submission; well-known Regulation; hard-won legislation

adviser

not advisor

affect/effect

Example: rules in the style guide had no **effect** (noun) on the number of mistakes; the number of mistakes was not **affected** (verb) by rules in the style guide; we hope to **effect** (verb) a change in this.

ageing, not aging

write: aged 40–60 years [not 'age' and not 'to'; use en-dash (long hyphen '—'), not standard hyphen] (See also: 'Hyphens']

agency

Use Agency (with initial cap) if referring to a specific agency e.g. the EMA

aggravate

to make worse, not to annoy

all right

is right; 'alright' is not all right

amid

not 'amidst'

among or between?

'between' is not limited to two parties. It is appropriate when the relationship is essentially reciprocal, e.g.: differences between the members of ICH; harmonisation between the ICH countries. 'Among' is used for distributive relationships: shared among the EU member states, etc

Use 'among' rather than 'amongst'

anticipate

take action in expectation of; not synonymous with expect

apostrophes

Use apostrophes in: five years' experience; two days' time; 12 years' exclusivity; where the time period (two days) modifies a noun (time), but not in nine months pregnant or three weeks old, where the time period is adverbial (modifying an adjective such as pregnant or old) – if in doubt, test with a singular such as one day's time, one month pregnant

Apostrophes matter for clarity – consider these four phrases, each of which means something different:

- my colleague's patient's medications [i.e. a patient of my colleague]
- my colleague's patients' medications [i.e. patients of my colleague]
- my colleagues' patient's medications [i.e. a patient of my colleagues]
- my colleagues' patients' medications [i.e. patients of my colleagues]

appendix

plural, appendices

around or approximately

instead of 'around'

average, mean, median and mode

Although we loosely refer to the 'average' in many contexts (e.g. cost of developing a drug), there are two useful averages worth distinguishing.

- What is commonly known as the average is the mean: everyone's wages are added up and divided by the number of wage earners.
- The median is described as 'the value below which 50% of employees fall', i.e. it is the wage earned by the middle person when everyone's wages are lined up from smallest to largest. (For even numbers there are two middle people, but you calculate the mean average of their two wages.)
- The median is often a more useful guide than the mean, which can be distorted by figures at one extreme or the other.
- The mode is the most common data item.

B

bacteria

plural of bacterium, so 'the bacteria are'

Bachelor's degree

possessive apostrophe (and initial cap for 'Bachelor's')

benefited, benefiting

billion

one thousand million, not one million million
spell out in full, six billion people, US\$10 billion, etc

brackets in speech

Square brackets are used in direct quotes to provide essential information which has not been given by the speaker. E.g. 'Accurate guide prediction [that CRISPR provides] and off-target identification will be of immense value for this newly developing field and therapeutics,' said Neville Sanjana, Associate Professor of Biology at NYU.

but, however

These words should not be used to connect two compatible statements. The use of 'in contrast, however' or 'but, however' says the same thing twice.

C

Chair or Chairperson

Not Chairman or Chairwoman

clinical trials

Phase I, II, III not Phase 1, 2, 3

collective nouns

nouns such as committee, company, team, regulatory agency, take a singular verb or pronoun when thought of as a single unit, e.g. (*apply strict usage of singular*)

- the agency gave its unanimous approval to the plans
- the agency gave its thoughts on the new legislation

companies

always in the singular, e.g. GlaxoSmithKline is launching a new product
always spell out in full, e.g. GlaxoSmithKline not Glaxo, or GSK.

compare(d) to/with

(see explanation below, but will almost always be 'compared with' in *Regulatory Rapporteur* copy)
the former means liken to, the latter means make a comparison; so, unless you are specifically likening someone or something to someone or something else, use compare with. For example, the CEO compared himself to Albert Einstein because he believed he was like Einstein; I might compare him with Einstein to assess their relative merits

comprise

it consists of; it comprises ('comprise of' is wrong)

conflicts of interest

(not conflicts of interests, or conflict of interests)

convince/persuade

having convinced someone of the facts, you might persuade them to do something

COVID-19

not Covid-19

CTA

Can mean clinical trial application (I/c) or clinical trial authorisation or clinical trial assay so check with author if unclear

D

data

takes a plural verb: the data were checked

defuse

render harmless; **diffuse** = spread around

different from

not different to or than

disk

not disc

due to/owing to

For example, compare: 'It was difficult to assess the changes due to outside factors,' with: 'It was difficult to assess the changes owing to outside factors'. The first says the changes that were a result of outside factors were difficult to assess, the second says outside factors made the changes difficult to assess (if in doubt, **because of** can be substituted for owing to, but not due to)

'due to' vs 'because of' (*are not interchangeable*)

Use 'due to' only to modify nouns. (Usage of 'due to' is correct if the sentence makes sense when 'due to' can be replaced with 'caused by').

Use 'because of' to modify verbs.

- **Due to** (presents reason for a noun)
The traffic jam was due to a terrible accident at the intersection.
- **Because of** (presents reason for an action)
The traffic jam happened because of a terrible accident at the intersection.

In the 'due to' example, the verb before due to is while in simple example sentence whereas in the 'because of' example, because of is preceded by the verb happened. Please note that 'is' presents the state of the

subject and happened denotes an action. Paying attention to the verb in the clause these phrases associate with can help determine whether the sentence must use due to or because of.

E

e.g./i.e.

To appear with each letter, followed by a stop and without commas on either side or any other punctuation.

- *exempli gratia*: ‘for the sake of example’.
- *id est*: ‘that is’ / ‘in other words’.

efficacy vs effectiveness

- **efficacy**: The extent to which an intervention does more good than harm under ideal circumstances.
- **relative efficacy**: The extent to which an intervention does more good than harm, under ideal circumstances, compared with one or more alternative interventions.
- **effectiveness**: The extent to which an intervention does more good than harm when provided under the usual circumstances of healthcare practice.
- **relative effectiveness (aka comparative effectiveness, US)**: The extent to which an intervention does more good than harm compared with one or more intervention alternatives for achieving the desired results when provided under the usual circumstances of healthcare practice.

*Definitions developed by the EU High Level Pharmaceutical Forum, ‘[Core principles on relative effectiveness, Final report 2005–2008](#)’.

enrol, enrolling, enrolment

et al.

not et al or et. al or et. al. or Et al or Et Al

EU

Formerly EC (European Community); before that EEC (European Economic Community)

EU presidents

There are three, so don’t say ‘EU President’ or ‘President of the Union’ without making clear which you mean: President of the European Commission, President of the European Parliament, or holder of the rotating presidency (technically ‘President in Office of the Council of the European Union’), which rotates among the EU member states every six months

EudraLex

the sets of rules and regulations governing medicinal products in the EU

EudraVigilance

European Union Drug Regulating Authorities Pharmacovigilance

the European data processing network and management system for reporting and evaluation of suspected adverse reactions during drug development and following the marketing authorisation of medicinal products in the European Economic Area (EEA).

F

fewer or less?

fewer means smaller in number, e.g. fewer drugs; less means smaller in quantity, e.g. less water.

focused, focusing

fulfil, fulfilling, fulfilment

G

G7

Canada, France, Germany, Italy, Japan, the UK and the US.

government

lower case; not Government

Great Britain vs the UK

England, Wales and Scotland; if including Northern Ireland, use the UK

H

headquarters

can be used as a singular ('a large headquarters') or plural ('our headquarters are in London'); HQ, however, takes the singular

Heads of Medicines Agencies

all plural

healthcare

one word

homing in, honing

not honing in

homogeneous vs homogenous

- **homogeneous** uniform, of the same kind
- **homogenous** (biology) = having a common descent
the latter is often misspelt/misused for the former

Huntington's disease

not Huntingdon's

formerly known as Huntington's chorea

I

i.e./e.g.

see [e.g./i.e.](#)

immune to

not immune from

impracticable vs impractical:

- impracticable = impossible, it cannot be done
- impractical = possible in theory but not workable at the moment

inadmissible

not '-able'

Indian (former) placenames

- Bombay is **Mumbai**
- Madras is **Chennai**
- Calcutta is **Kolkata**
- Bangalore is **Bengaluru**

infer/imply

to infer is to deduce something from evidence; to imply is to hint at something (and wait for someone to infer it)

inpatient, outpatient

no hyphens

install, instalment

instil, instilled, instilling

internet

l/c

introductory phrases

such as '**However**', '**Nonetheless**', '**Instead**', should all be followed by a comma

-ise

not -ize at end of word, e.g. maximise, synthesise (see 'Spelling')

its, it's (never its')

If you can substitute the word with 'it is' or 'it has' then you want the contraction 'it's'

- **It's** a new clinical trial
- **It's** been more than a year

If you can replace the word with 'his' or 'her' and it makes sense, then you want the possessive 'its'

- The organisation is strong, but **its** rules are weak
- The world is **its** oyster

J

Johns Hopkins University

not John Hopkins

judgment

not judgement

L

labelled, labelling

led

use this as past tense of the verb 'lead'

less/fewer

see [fewer or less](#)

lifelong

one word

licence noun; **license** verb

a company might apply for a pharmaceutical industry **licence**; they might be ready to **license** their company; or they might have an understanding of pharmaceutical **licensing**

light year

a measure of distance, not time

like vs such as

'like' excludes; 'such as' includes: 'Drugs like aspirin are highly effective' suggests the writer has in mind, say, ibuprofen or codeine; the author actually means 'drugs such as aspirin'.

liquefy

not liquify

M

Master's degree

possessive apostrophe (and with initial cap)

Médecins sans Frontières

international medical aid charity (don't describe it as French)

member states

do not abbreviate to MS unless used over three times in one standard length article

Medicaid, Medicare

both US federal health insurance programmes, Medicare primarily covers people over 65 and has no financial requirements for eligibility; Medicaid is targeted at those on low incomes

myriad

a large, unspecified number; use as an adjective (there are myriad patients in the trial) or a noun (there is a myriad of patients in the trial), but not ‘myriads of’

N

neither/none

none is singular (none of them is) and so is ‘neither’ (neither of them is)

the Netherlands (not The Netherlands)

not Holland, which is only part of the country; use Dutch as the adjective

O

Oceania

a preferable term to Australasia, it is sometimes divided into Near Oceania and Remote Oceania, and comprises, according to the UN:

- **Australia/New Zealand**
- **Melanesia** (Fiji, New Caledonia, Papua New Guinea, Solomon Islands, Vanuatu)
- **Micronesia** (Guam, Kiribati, Marshall Islands, Federated States of Micronesia, Nauru, Northern Mariana Islands, Palau)
- **Polynesia** (American Samoa, Cook Islands, French Polynesia, Niue, Pitcairn, Samoa, Tokelau, Tonga, Tuvalu, Wallis and Futuna Islands)

one in six, one in 12, etc.

should be treated as plural. Compare ‘more than one in six COPD sufferers is 65 or older ...’ with ‘more than one in six COPD sufferers are 65 or older ...’. Grammatically, we are talking not about the noun ‘one’ but the noun phrase ‘one in six’, signifying a group of people, i.e. the phrase represents a proportion. Equally, ‘17%’ or ‘one-sixth’, take plural verbs. ‘Two out of every seven’ and ‘three out of 10’ take plurals too.

organisations

always in the singular, e.g. TOPRA is an organisation for regulatory affairs professionals. It has members worldwide... (see *companies / collective nouns*)

Use English spelling (‘organisation’), unless the organisation refers to itself differently (e.g. The World Health Organization’)

P

Phase I, II, III, IV (not phase and not **1, 2, 3, 4**).

Note: when writing, keep together by using non-break space [CTRL + SHIFT + Spacebar on PCs; APPLE + Spacebar on Macs]

Pipeline

one word

planning

not 'forward planning' (tautological)

practice

noun; **practise** verb

preventive

not preventative

principal vs principle

principal = first in importance; principle = standard of conduct

programme

for computer software and clinical trial programme (unless part of a US-named programme, e.g. the US FDA's Medical Device Single Audit Program – or the verb 'to program')

publicly

not publically

R

'with regard to' or 'with regards to'?

with regard to (no 's') means about or concerning. The other expression meaning the same thing is 'as regards'. ['Regards to' (with 's') relates to sending your regards (good wishes) to someone.]

S

sub-Saharan

T

targeted

taskforce

one word

that or which?

'that' defines, 'which' gives extra information (often in a clause enclosed by commas): 'this is the house that Jack built'; but 'this house, which Jack built, is falling down';

Tip: note that the sentence is still correct without 'that', but not without 'which'

treatment-naïve

hyphenate

trialling

trillion

a thousand billion (1 followed by 12 noughts), abbreviate like this: \$25tn

U

uncharted

not unchartered

universities (especially American)

Take care: 'University of X' is not the same as 'X University' – most US states have two large public universities, e.g. University of Kentucky and Kentucky State University, University of Illinois/Illinois State University, etc.

NB: Check spellings, e.g. **Johns** Hopkins University, not **John** Hopkins; **Stanford** University, not **Stamford**.

up to date

no hyphens if it is used as an adverb phrase, e.g. 'the records are up to date'.

Use hyphens if it is used as an adjective, e.g. 'in an up-to-date fashion.'

V

very

usually meaningless

veto, vetoes, vetoed, vetoing

vice-chair, vice-chancellor, vice-president

upper case if someone's direct title and hyphenate

W

wellbeing

one word

well-known

hyphenate if descriptive, e.g. well-known formula; not if the formula is well known

which or that?

see [that or which](#)

while

not whilst

who or whom?

If in doubt, ask yourself how the clause beginning who/whom would read in the form of a sentence giving he, him, she, her, they or them instead: if the who/whom person turns into he/she/they, then 'who' is right; if it becomes him/her/them, then it should be 'whom'.

In this example: 'Johnson was criticised for praising Cameron, whom he admired' – 'whom' is correct because he admired 'him'.

But in 'Johnson praised Cameron, who he thought was right' – 'who' is correct, because it is 'he' not 'him' who is considered right.

X

Xerox

TM; use **photocopy**

x-ray

hyphenate