

Practical applications of an IFU scorecard

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70%

of HF practitioners cite
IFU design & content
as one of the **most common drivers of FDA requests.**

10+

Guidance sources
that may be referenced
throughout IFU
scorecard reviews

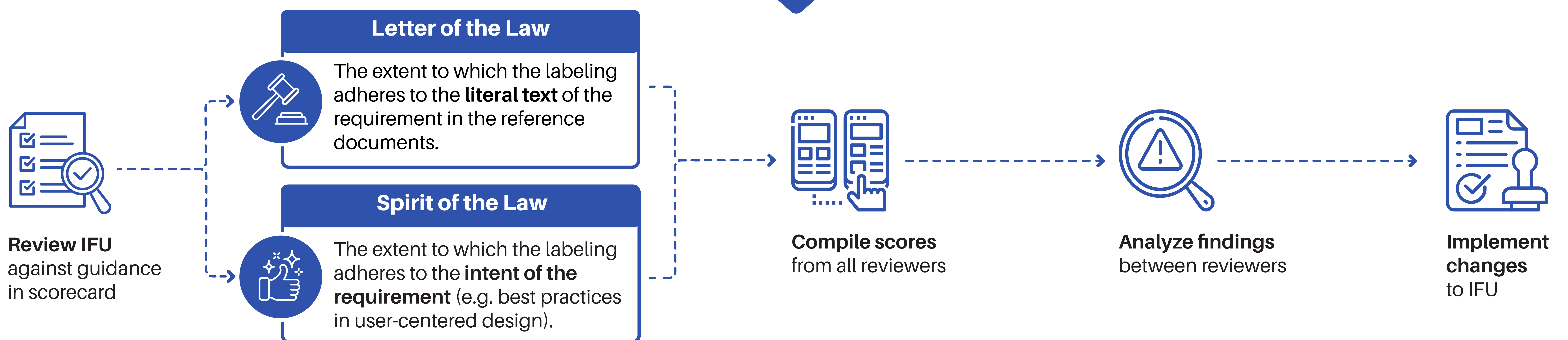
1

IFU-related guidance is
all in one spot
to ensure everything
is captured

What is an IFU Scorecard?

A **framework** for HF practitioners to **evaluate their IFU** and understand **areas to improve** based off regulatory guidance. This work includes **prescriptive and directional recommendations** on the content and format, and identifies **where guidance is or is not met.**

IFU scorecard process



Example #1

Step 8 Close one (1) nostril.

- With your free hand, use a finger to gently press on one (1) nostril to close it (see **Figure 8**).
- Continue to breathe normally through your mouth.

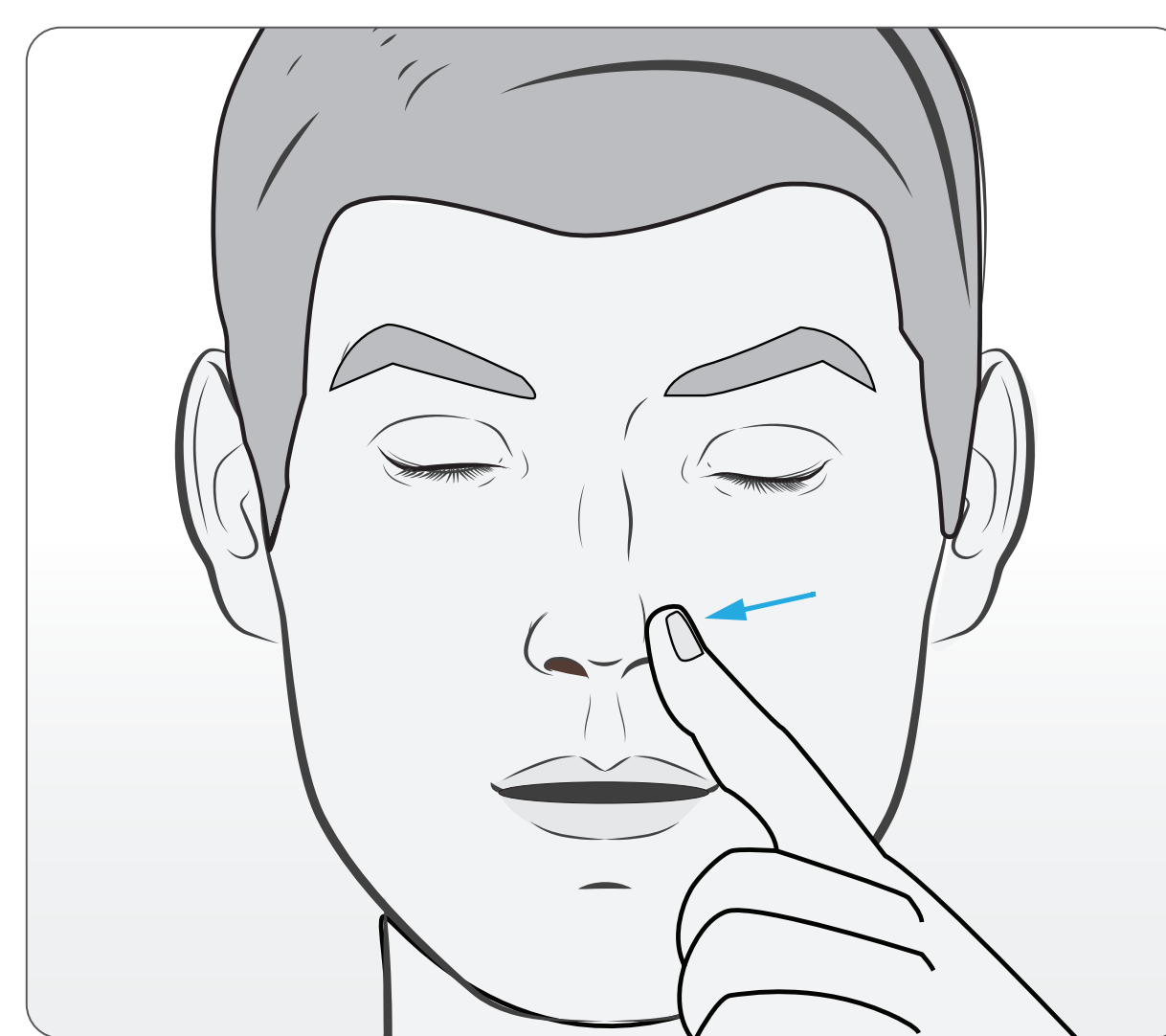


Figure 8

Step heading label

Step headings should be noted as "Step 1, Step 2, etc."

intent: Clarity
(CDER/CBER 2019)



Figures use numeric labels

Visuals should be labeled alphabetically in bold type (such as Figure A, Figure B, etc.)

(CDER/CBER 2019)

Example #2

Step 12 Confirm dosing is complete.

- You have successfully received a full 24-hour extended release dose if you have:
 - » Used one (1) device.
 - » Sprayed device one (1) time into one (1) nostril (see **Figure 13**).

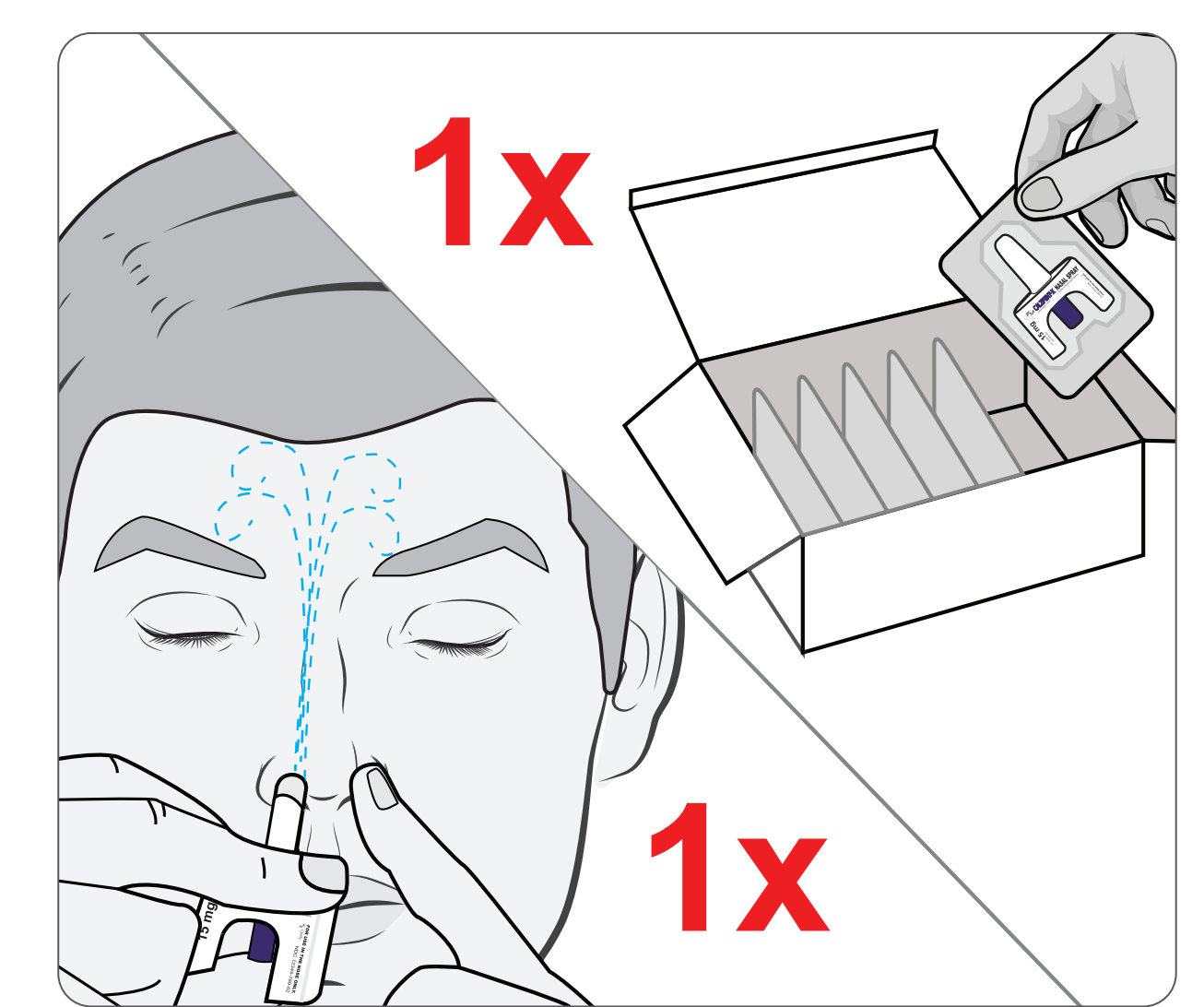


Figure 13

Appropriate font used

Sans-serif font should be used for all text in the IFU, with font size no smaller than 10 points.

Intent: Clarity
(CDER/CBER 2019)



Disposal info not present

IFU ends at Step 12. Disposal info should be described under: Disposing of [Drug Name].

Intent: Safety
(CDER/CBER 2019)