ICH M2 File Format Criteria

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Number	Category	Type	Criteria	Required / Desired
1	Functionality	Data	Supports the transfer of data in a manner which can then be extracted and used	R
2	Functionality	Image	Supports lossless compression	D
3	Functionality	Narrative	Supports navigation within and between files (e.g., bookmarks, hyperlinks)	R
4	Functionality	Narrative	Supports tagging information elements for extraction into other formats and databases	D
5	Functionality	Narrative	Supports inclusion of tables while preserving detailed information about formatting of such tables and the relationship of such tables to surrounding text.	D
6	Functionality	Narrative	Supports inclusion of graphics while preserving detailed information about formatting of such graphics and the relationship of such graphics to the surrounding text.	D
7	Functionality	Narrative	Supports inclusion of text while preserving detailed information about formatting of such text.	D
8	Functionality	Narrative	Supports UTF-8	R
9	Functionality	Narrative	Supports UTF-16	D
10	Functionality	Narrative	Fonts can be embedded	R
11	Functionality	Narrative	Font subsets can be embedded	D
12	Functionality	Narrative	Narrative content is stored in a form that enables it to be extracted as text	R
13	Functionality	Audio	Supports a variety of bit resolutions and sample rates (e.g. WAVE or Broadcast Wave Format)	D
14	Functionality	Audio	Supports lossless compression (e.g. WAVE or Broadcast Wave Format)	D
15	Functionality	Digital Video	Supports a variety of record/playback resolutions (e.g. MPEG, AVI)	D
16	Functionality	Digital Video	Supports a variety of frame rates (e.g. MPEG, AVI)	D
17	Functionality	Digital Video	Supports compression (e.g. MPEG)	D
18	Functionality	Digital Video	Supports a wide range of CODECS (e.g. MOV, MPEG-2 or MPEG-4)	D
19	Functionality	Digital Video	Supports full frame (no interframe compression) video (e.g. AVI)	D
20	Functionality	Digital Video	Supports a lossless video (e.g. JPEG 2000 MXF)	D
21	Functionality	All	Contains basic descriptive, technical and administrative metadata	D
22	Openness	All	Free tools are available for consuming/reviewing	R
23	Openness	All	Free tools are available for creating	D

24	Openness	All	Open standard, widely utilized	D
25	Openness	All	Complete specifications are publicly and openly documented and accessible so that it is clear how the information is represented	D
26	Openness	All	Not encumbered by any copyrights, patents, trademarks or other restrictions so that anyone may use it at no monetary cost for any desired purpose	D
27	Openness	All	Platform independent, machine readable, and made available to the public without restrictions that would impede the re-use of that information	D
28	Openness	All	The format's specification is/was developed through a publicly visible, community driven process (e.g., W3C, OMG, IETF, OASIS)	D
29	Openness	All	The format's specification is affirmed and maintained by a vendor-independent, international standards organization (e.g., ISO)	D
30	Openness	All	If the format allows for non-standardized extensions it must provide a means to disable or prohibit use of such extensions.	D
31	Openness	All	The format is supported across many software and hardware systems made by different manufacturers	D
32	Openness	All	The format does not require mechanisms (e.g., encryption) that would prevent the preservation of content (i.e., archiving)	D
33	Reliability	All	The format's specification is stable (e.g., functioning change-management process, versions are backward compatible)	D

This document is intended to be used as guidance when considering electronic file formats for different use cases in regulatory submissions. These use cases would include but not be limited to primarily text (narrative) files, image files, data files and specialized formats (e.g. MOL for chemical structures, ZIP for compressed archive).

** Note - ICH recommendations for any file format should carefully specify any restrictions in the use of the format such that any vendor-specific features are not used.