

EWG M2 Recommendation to the ICH Assembly

Electronic Standards for the Transfer of Regulatory Information (ESTRI)

Two-Dimensional (2D) Barcode Recommendation

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Title: Two-Dimensional (2D) Barcodes

Background:

The linear or one-dimensional (1D)¹ barcode has been acknowledged standard for representing data in a visual, machine-readable form. It is also recognized that there is need to identify a standard format for two-dimensional barcodes (2D barcode). A 2D barcode is a machine-readable code that may be represented as a Data Matrix² code or a Quick Response (QR)³ code. Both QR codes and Data Matrix codes are public domain codes and are royalty free.

Published specifications and print requirements for each code are available from the International Organization for Standardization (ISO).

- Requirements for Data Matrix codes are specified under the ISO/IEC 16022 international standard.
- Requirements for QR codes are specified under the ISO/IEC 18004 international standard.

Recommendation:

- This recommendation is applicable to those regions who are exploring the implementation of 2D Barcodes.
- ICH M2 EWG recommends the Data Matrix and/or Quick Response codes per ISO/IEC 16022 and ISO/IEC 18004.

Conditions:

- Regional laws/requirements determine if and which 2D barcode (Data Matrix or QR Code) is acceptable and where it is to be applied.
 - Sponsors should adhere to the recommended standards/specifications as identified by the regulatory authority.

Note: This document is not recommending the deprecation of the linear barcode; please refer to regional laws/guidance on the adoption of barcodes.

Remarks:

- Any proposed data carrier recommendation for 2D barcodes will be focused on 2D barcodes only (non-linear).

¹ ISO/IEC 15426-1:2006 as the Information technology — Automatic identification and data capture techniques — Bar code verifier conformance specification — Part 1: Linear symbols

² A Data Matrix is a two-dimensional code consisting of black and white "cells" or dots arranged in either a square or rectangular pattern, also known as a matrix. The information to be encoded can be text or numeric data.

³ A QR code (Quick Response code) is a type of two-dimensional matrix barcode, invented in 1994, by Japanese company Denso Wave. A barcode is a machine-readable optical image that contains information specific to the labelled item. QR codes use four standardized modes of encoding (i) numeric, (ii) alphanumeric, (iii) byte or binary, and (iv) kanji.