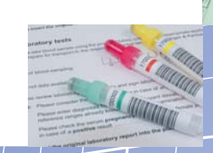


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## About PharmaForms

PharmaForms responds with its production facilities to the demand of the pharmaceutical document flow installations. We believe that barcodes can contribute to an efficient design of your workflow.

Over the past years we have been promoting the use of barcodes and have implemented many barcode based identification systems. Through the experience and expertise that we have accumulated and through close cooperation with solution providers we know very well how to achieve utmost system reliability.

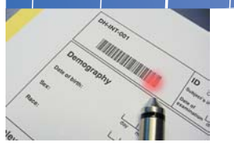
Make use of our expertise:
We would like to advice you on barcode implementation and print your documents for you.

PharmaForms
A Division of the Diagramm Halbach Group

- automatic archiving
- high speed digitalisation
- preparation of eCTD
- reduction of cost
- enhancement of monitoring

# PharmaForms

## TECHNICAL ASPECTS OF BARCODED CRFs



- trial acceleration
- workflow optimisation
- meeting timelines

# *Technical aspects of barcoded CRFs*

## TECHNICAL INTRODUCTION

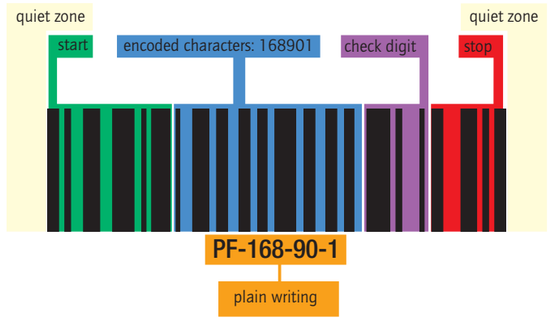
Codes often have the purpose to hamper communication between parties, just think of the multitude of military and civil encryption codes currently in use.

Barcodes, on the contrary, are designed to enable communication. They  make the information flow from paper to computers happen. They serve the aim of automised identification.

Computers rely on binary information structure. In order to feed them with information we have to encode the respective data into a binary format, too. Barcodes all encode characters into a binary, computer interpretable syntax: bars (“1“) and spaces (“0“).

The opto-electronic interface between paper and computer is the scanner. It emits light rays and reads its reflection on the bars and translates it into sequences of 1s and 0s transforming them finally into ASCII-characters.

## GENERIC STRUCTURE OF BARCODES




**QUIET ZONES** (approx. 2-5mm) before and after the barcode eliminate confusion with pre-and succeeding barcodes or other objects.

**START AND STOP CHARACTERS** enable omnidirectional scanning.

**THE CHECK-DIGIT** allows proofing of the correct reading by the scanner itself, although it is nowadays not really necessary anymore as the processing software checks the barcode on plausibility automatically.

## THE FOLLOWING POINTS ARE CRUCIAL

to the implementation of barcodes into your infrastructure:

1. Defining the appropriate underlying code-system
2. Choosing the appropriate barcode symbology
3. Complying with print requirements

## DEFINING THE APPROPRIATE CODE-SYSTEM

An optimal identification system

- **A)** is as easy and short as possible and
- **B)** as complex as necessary and
- **C)** covers all eventualities that may arise in the future

Most identification systems in clinical trial environments comply with the following minimalistic code system that has proven to be optimal (in accordance to the optimality condition cited above):

- 5 digits for study ID (fix)
- 4 digits for document ID (incremental)
- 3 digits for page ID (incremental)

Bear in mind that barcodes are nothing but a vehicle between paper and computer. The processing software uses relational databases and filters in accordance to your requirements. The power of relational databases allows to separate the code system used for the barcodes from the nomenclature that is used for human understanding. The database retranslates the code system back into an extensive nomenclature that makes sense to humans.

It is recommendable to integrate a line of plain writing below the barcode. This writing reflects the extensive nomenclature.


## CHOOSING THE APPROPRIATE SYMBOLOGY

Code 128, Code 2/5 interleaved, Code 3/9 and Codabar are the most popular current codes.

### CODE 128

Code 128 encodes all upper and lower case letters, all numbers as well as punctuation marks (128 characters altogether). Code 128 works with 3 different code syntaces (addressable through shift-characters) that enable a very dense encoding.

- **A)** encodes all 128 ASCII-characters
- **B)** odd and even number of digits encodable
- **C)** preferable when encoding alphanumerical characters

### CODE 2/5 („TWO OF FIVE“) INTERLEAVED

The name is derived from the code’s syntax: Each character is encoded by 5 elements of which 2 are big and 3 are small. As the spaces between the bars serve as elements as well, two characters are encoded in one code unit: always two characters are interleaved.

- **A)** encodes only numerals
- **B)** requires an even number of encoded characters
- **C)** preferable when encoding numerical characters only

## COMPLYING WITH PRINT REQUIREMENTS

The quality of the barcode print is essential to the whole system. It is the print quality that determines the strength of the weakest link: The transformation from analogous to digital data, the information flow from paper via scanner to the computer.

The interpretability of the barcode by the scanner depends namely on

- The reflectability of the ink
- The contrast of the print
- The barcode’s height
- The barcode’s width
- The barcode’s environment