



## Swedish Government Mandate

## Electronically structured coded PI Swedish (human+vetinary)

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Pre study: 2018  
Project start: 2020?



# Possibilities for new formats.

## Content remains.

### Open data - Format tailored to reader

PAPER/WORD  
FORMAT

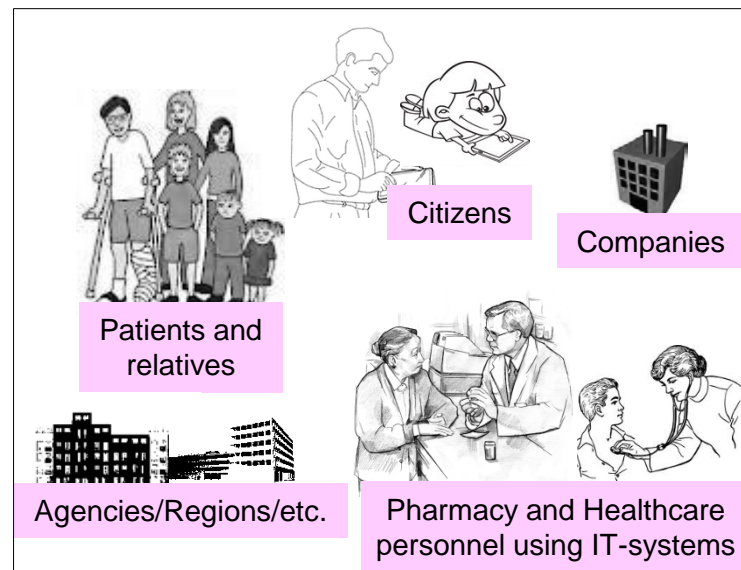


PDF ON SCREEN



# Involve ALL

- User knowledge – what is needed?
  - Personal interviews



## Multidisciplinary project

- PI knowledge – what is required?
- IT knowledge – what is possible?
- Project leader – make things happen. Don't wait!

# Structured format

– **how?** As today - FASS

– **who?** **MAH** in national phase,  
in an online solution  
provided by the MPA

QRD template mapping:

- **Preselected QRD template**
- **Basic elements from register sources**
- **Preselected standard phrases**

Drop down menu ▼


- **Free text mass**  
can be given attributes behind the system  
regardless term

**coded**  
(*MedDRA/IDMP/national indication  
registers/etc*)

## 1. NAME OF THE MEDICINAL PRODUCT

(Invented name) (strength) (pharmaceutical form)

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

(Active substance) (amount) (unit)

**Excipient(s) with known effect**

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

(Pharmaceutical form)

Select standard sentence for information on dividing of tablets ▼

The score line is only to facilitate breaking for ease of swallowing  
and not to divide into equal doses.

The score line is not intended for breaking the tablet.

The tablet can be divided into equal doses.

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

(Indication) (Age) (Sub population)

*(Linked to code) Example: Diabetes mellitus type 2*

### 4.8 Undesirable effects

*(Linked to code) Examples:*

*Pyrexia*

*High body temperature*

*Fever*

} *Regardless term, coded into MedDRA term fever*

USABILITY



All Swedish  
PI on one  
web page

IMPROVEMENTS  
FROM TODAY



**Choose relevant info**  
indication  
side effects  
tailor personal relevant info

**SmPC**  
**LABEL TEXT**  
**PACKAGE LEAFLET**

**Standardisation**  
\*table formats preselected  
\*standard sentences in  
drop down menu

**Common tool**  
\*unnecessary  
e-mails avoided

QUALITY

**Comparison**  
Individual patient's  
possible interactions  
from his/her  
medicines list

Error due to wrong version  
avoided

# Dear Santa...



- **PI electronically structured and coded already in the european phase of all procedures**
- **One EU common tool instead of one for each country**
- **QRD template in EU agreed xml format**
- **Thank you! Questions are welcome [kim.sherwood@mpa.se](mailto:kim.sherwood@mpa.se)**