



**Centre Hospitalier Intercommunal**  
**Robert Ballanger**

# Unique Device Identification of Surgical Instruments



**Centre Hospitalier Intercommunal**  
**Robert Ballanger**



# Summary



- Presentation of Robert Ballanger Hospital
- The evolution of the traceability of sterile medical devices
- The project of Unique Device Identification
- Our next GS1 projects





# Robert Ballanger Hospital

- Intercity hospital serving a population of 400,000 persons
- 650 beds
  - 450 beds in acute care (medical, chirurgicall and maternity)
  - 200 psychiatry beds
- Outpatient clinic and pharmacy inside Villepinte detention center
- CDG airport hospital





# Traceability of Medical Devices in Robert Ballanger Hospital



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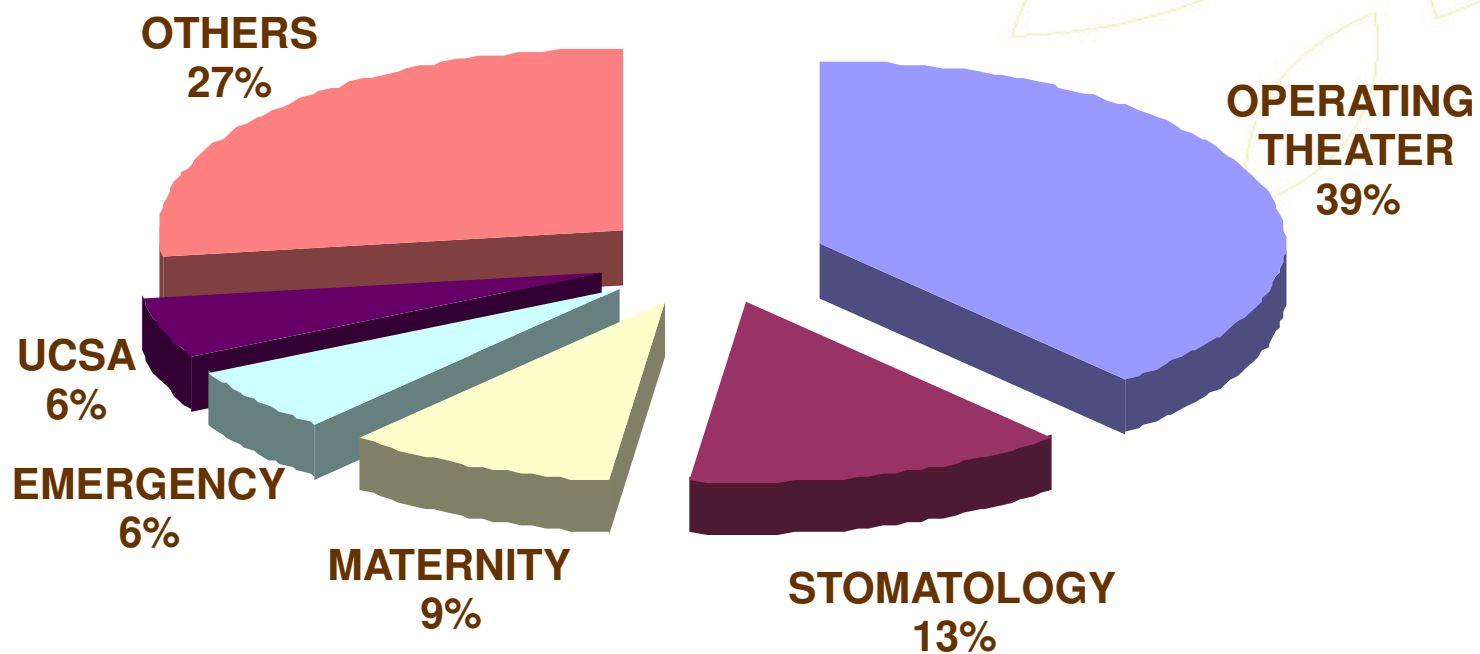
# Sterilization unit



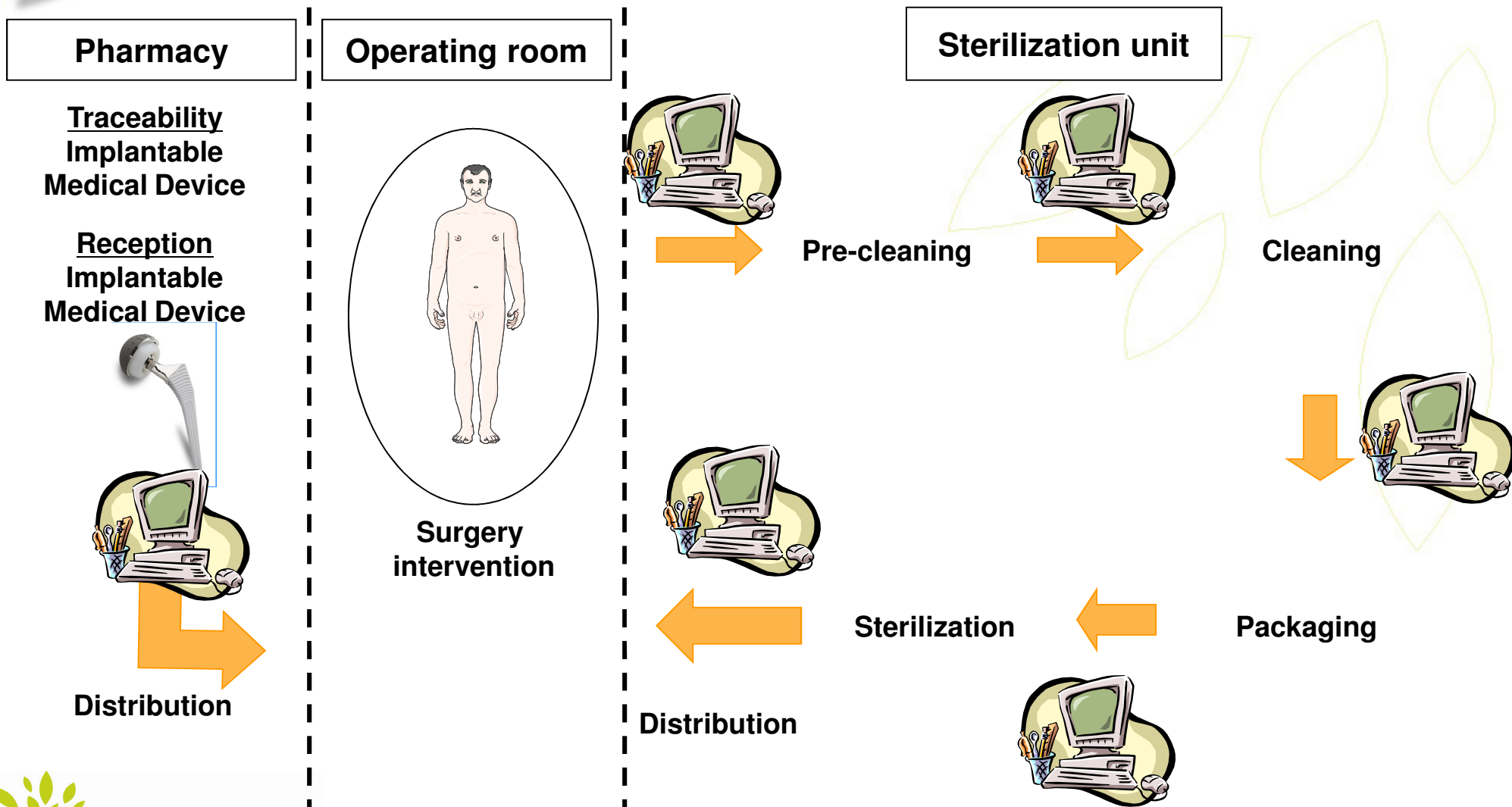
- 120 000 sterilized devices per year
- 20 000 surgery boxes per year



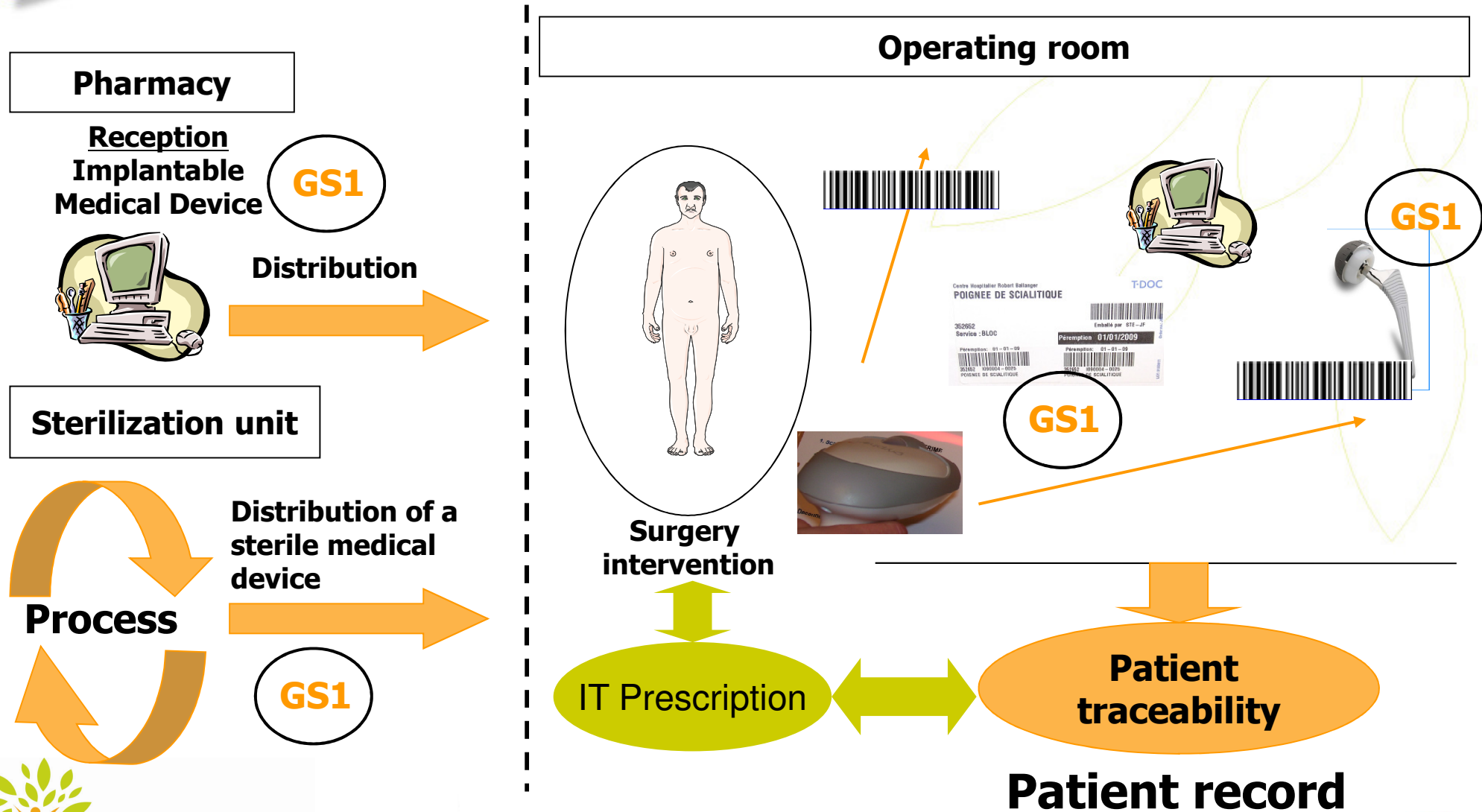
# Repartition of the sterilisation unit activity



# Traceability



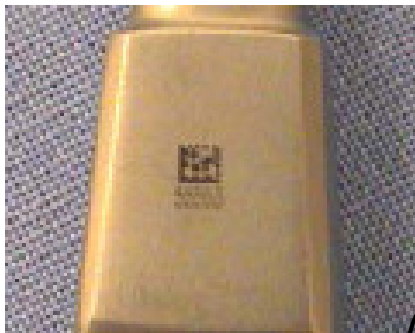
# Traceability of Medical Devices with GS1 Standards



# Unique Device Identification The CHIRB choice

## DATAMATRIX

### Laser



GS1

+

**Industrial tagging**  
**Easy reading**  
**Industrial treatment**  
**of instrument**

-

**Time to tag Devices**

### Infodot



+

**Easy and fast tagging**  
**Cost**

-

**Deterioration faster**  
**than the others**



# Traceability in year 2009

## The Robert Ballanger Hospital choice

| DATAMATRIX |                   | 2009  | % Traceability of instruments | % Traceability of sterilisations / year |
|------------|-------------------|-------|-------------------------------|---|
| INFODOT    | Clinical services | 4 000 | 35%                           |   |
| LASER      | Operating theater | 1 000 | 10%                           | 20%                                     |





# DATA MATRIX LASER



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# Non conformity of surgical boxes

**8.7% of No Conformity**

**Problem of packaging  
5 %**

**Quality of Instruments  
3.7%**

**Can be resolved by UDI**

**Can Not be resolved by UDI**

# Number of instruments to tag

6 Trays / reference

39 instruments / tray

1 reference

**Caesarean  
Tray**

Tray 1

Tray 2

Tray 3

Tray 4

Tray 5

Tray 6

| Article name                    | N°   | Quantity |
|---------------------------------|------|----------|
| BOITE INOX 42X18X9 CM           | B120 | 1        |
| MANCHE DE BISTOURI N° 4         | M330 | 1        |
| CISEAUX MAYO DROIT 16 CM        | C111 | 1        |
| CISEAUX MAYO COURBE 18 CM       | C112 | 1        |
| PINCE DISSECTION A/G 14 CM      | P124 | 1        |
| PINCE DISSECTION S/G 14 CM      | P125 | 1        |
| PINCES KOCHER A/G 14 CM         | P126 | 6        |
| PINCES KELLY DROITES S/G 14 CM  | P127 | 6        |
| PINCES KELLY COURBES S/G 14 CM  | P128 | 6        |
| PINCES A CHAMPS BACKHAUSS 12    | P129 | 4        |
| PINCE A PANSEMENT DROITE 24 CM  | P130 | 1        |
| PORTE-AIGUILLES MAYO-HEGAR 18   | A440 | 1        |
| PORTE-AIGUILLES DE DOYEN 14 CM  | A441 | 1        |
| ECARTEUR DE FARABEUF 12 CM      | E550 | 1        |
| ECARTEUR FARABEUF 15 CM         | E551 | 1        |
| VALVES DE KELLY 23 CM           | V660 | 2        |
| VALVES VAGINALES DE DOYEN 90 MM | V661 | 2        |
| PINCE DISSECTION S/G 20 CM      | D770 | 1        |
| PINCE DISSECTION A/G 25 CM      | D771 | 1        |

**234 instruments  
for the reference  
“Caesarean Tray”**



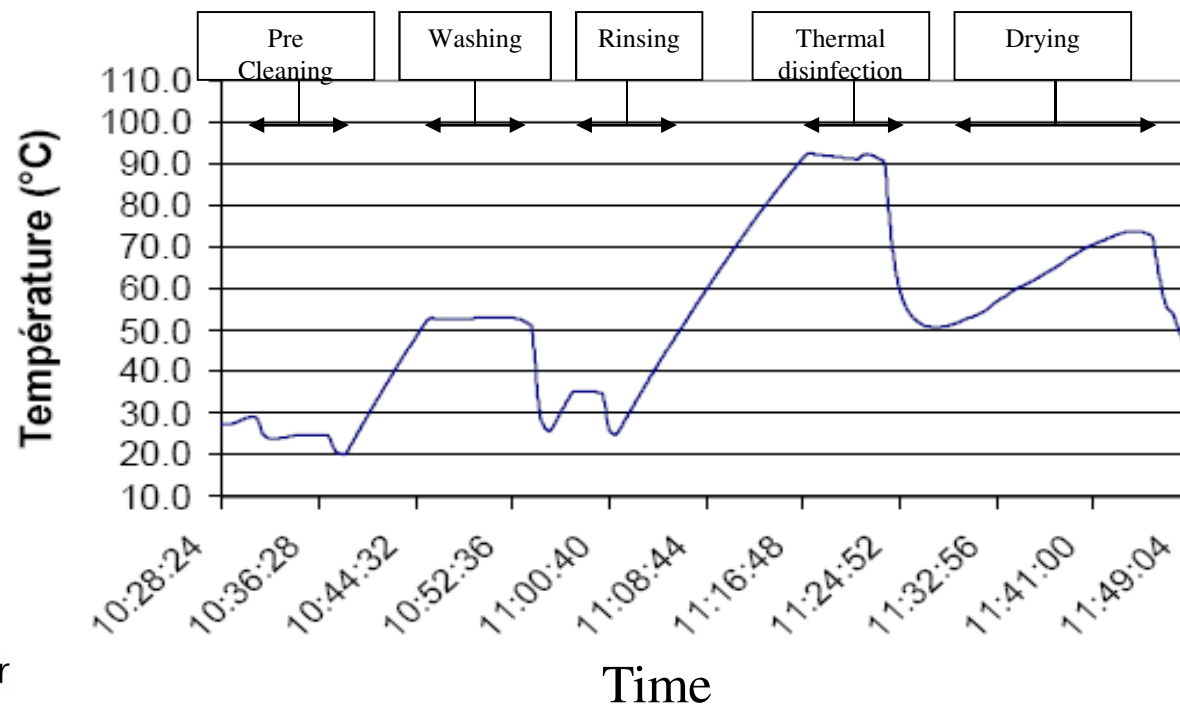
# Number of instruments to tag

|  | Surgical specialities |              |              |            |              |            |            |            |               |
|--|-----------------------|--------------|--------------|------------|--------------|------------|------------|------------|---------------|
|  | Orthopaedics          | Visceral     | Obstetric    | ORL        | Stomato      | Urology    | Infantil   | Ophtalmo   | Sum           |
| Number of references                     | 138                   | 30           | 15           | 34         | 53           | 32         | 14         | 15         | <b>331</b>    |
| Number of trays                          | 222                   | 78           | 51           | 72         | 98           | 54         | 25         | 33         | <b>633</b>    |
| Trays which can not be tagged (implants) | 60                    | 2            | 0            | 6          | 18           | 8          | 0          | 1          | <b>95</b>     |
| Number of instruments to tag             | <b>3 270</b>          | <b>1 899</b> | <b>1 107</b> | <b>945</b> | <b>1 673</b> | <b>712</b> | <b>672</b> | <b>382</b> | <b>10 660</b> |

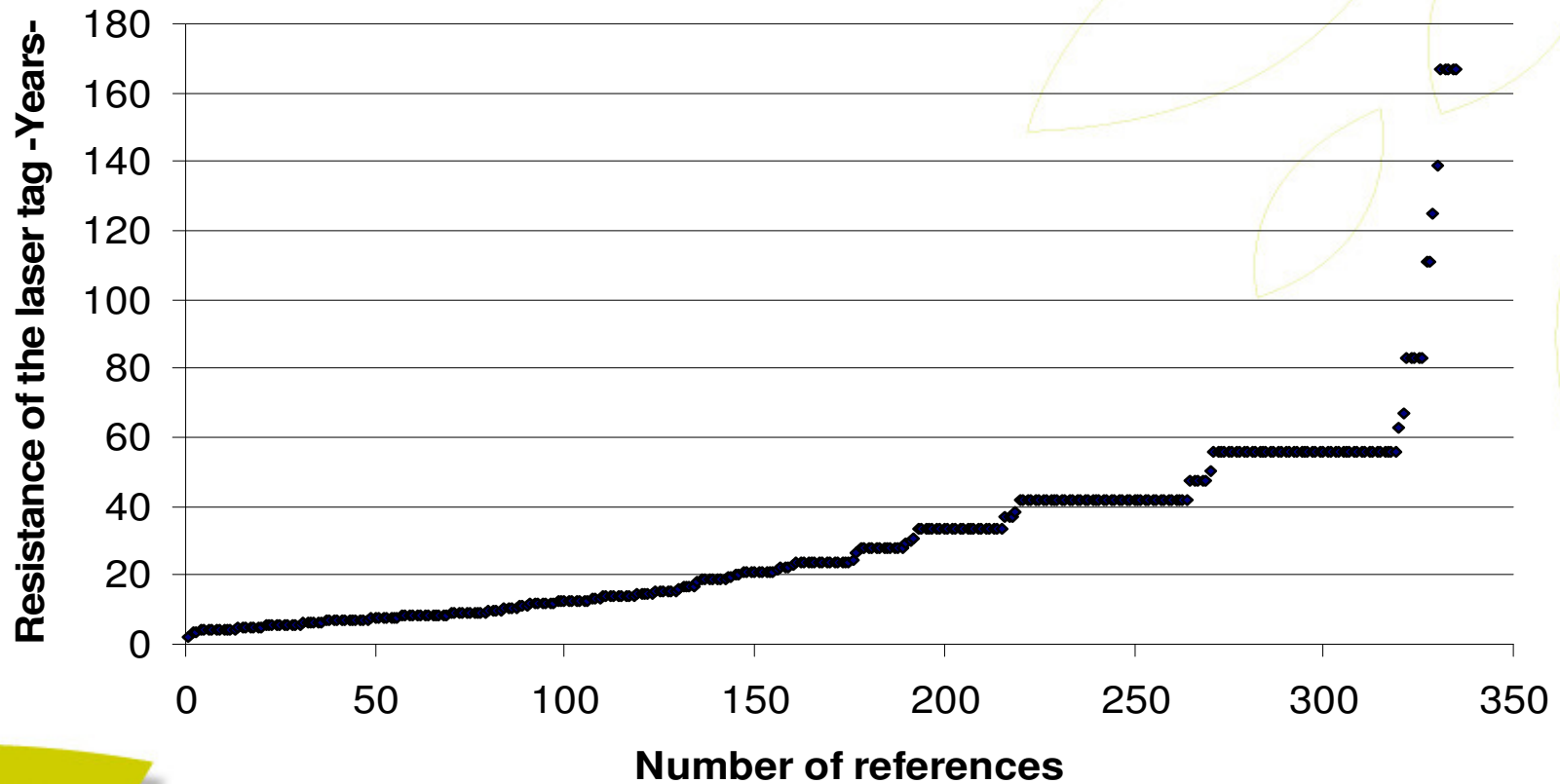


# Tag resistance to sterilisation

- Test on 8 different instruments :
  - 95% inox – 5% titanium
  - laser datamatrix, stamping, infodot, RFID
- Result : 100% lisibility on Inox laser marked instruments after 200 sterilisation cycles



# Resistance of the laser tag

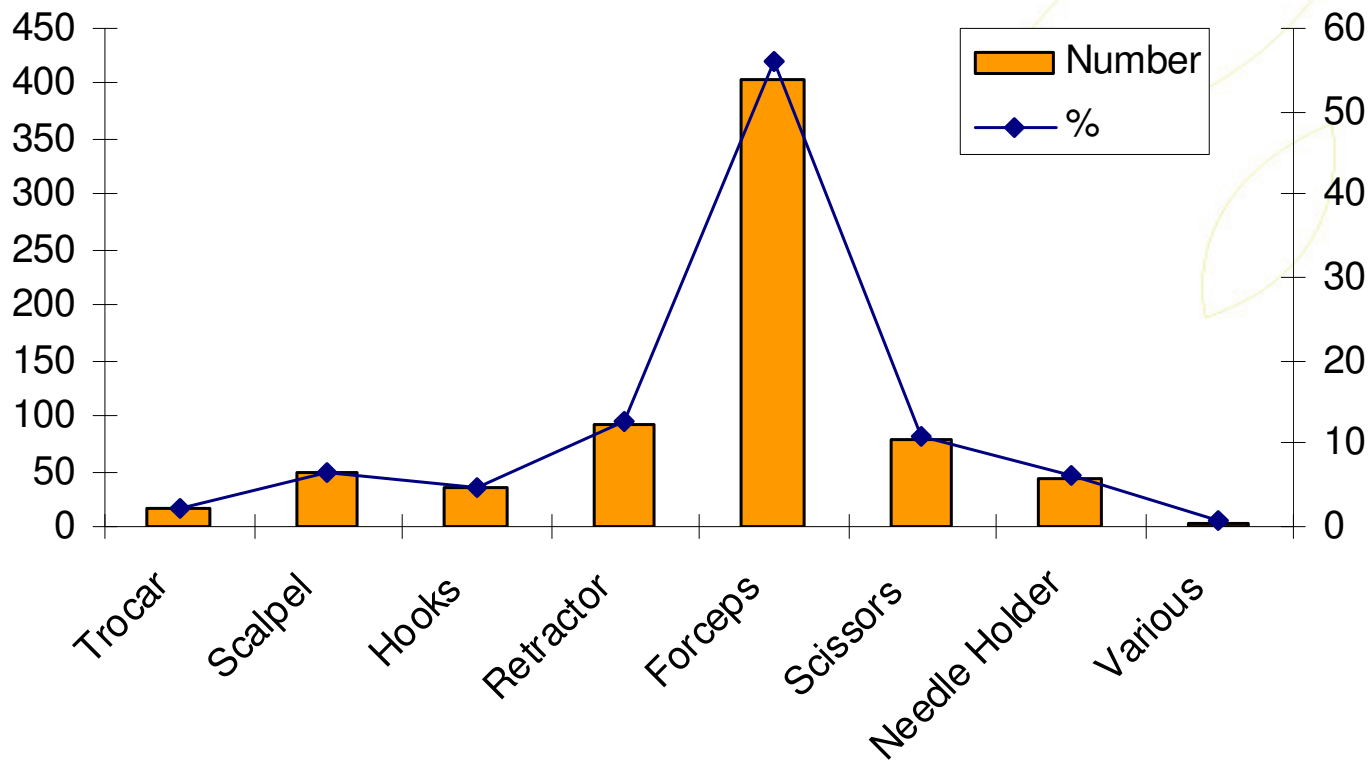


# Number of instruments to tag

Life time of the tags : 200 cycles

| Tag life time (LT) in years (based on number of sterilisation cycles / year) | N° references | N° Trays   | N° instruments | N° tagging / 10 years | N° tagging / 20 years |
|--|---------------|------------|----------------|-----------------------|-----------------------|
| LT < 2 years   | 1             | 3          | 30             | 161                   | 323                   |
| 2 years ≤ LT < 5 years   | 16            | 97         | 2 545          | 5 893                 | 11 787                |
| 5 years ≤ LT < 10 years  | 66            | 148        | 3 438          | 5 053                 | 10 106                |
| 10 years ≤ LT < 20 years   | 61            | 114        | 2 406          | 5 656                 | 3 589                 |
| 20 years ≤ LT  | 191           | 272        | 2 241          | 3 899                 | 2 241                 |
| <b>Total</b>   | <b>335</b>    | <b>634</b> | <b>10 660</b>  |                       |                       |
| Number of markings if life cycle of <u>instruments</u> is 10 years           |               |            |                | <b>20 663</b>         |                       |
| Number of markings if life cycle of <u>instruments</u> is 20 years           |               |            |                |                       | <b>28 045</b>         |

# Type of Tagged Instruments



N=719 Instruments Tagged



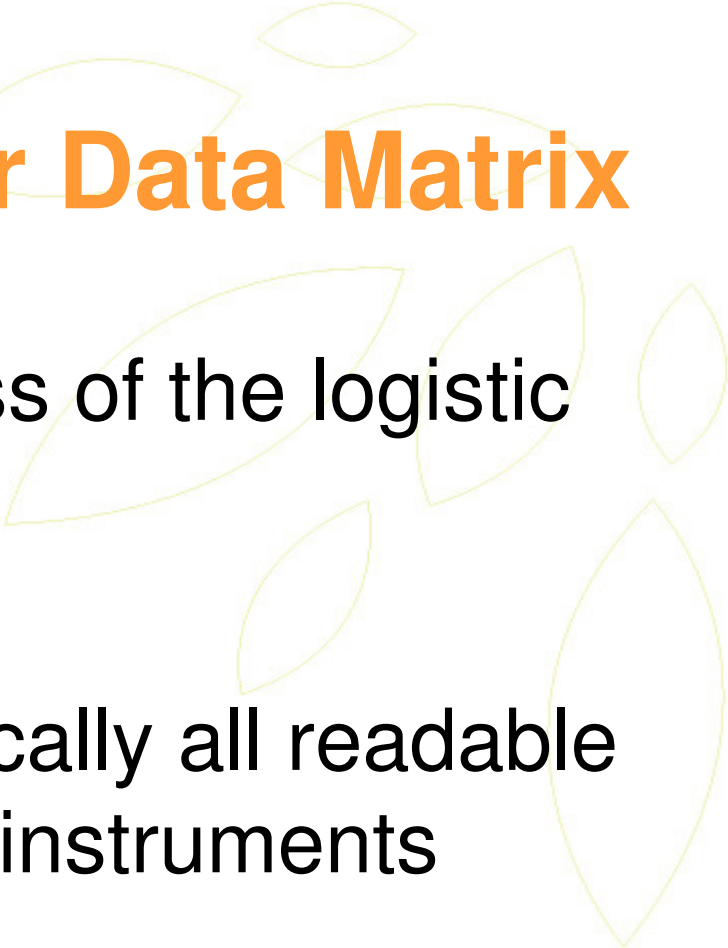
# Logistic data

- 360 instruments can be tagged a week
  - Depending on supplier (500 a week for our French supplier)
  - Depending on the numbers of instruments that can be sent per week
- Percentage of code readable : >97%
  - 100 % technically readable when tested after their laser marking
  - Our choice : keeping speed of work by not reading very small instruments





# Conclusion – Laser Data Matrix

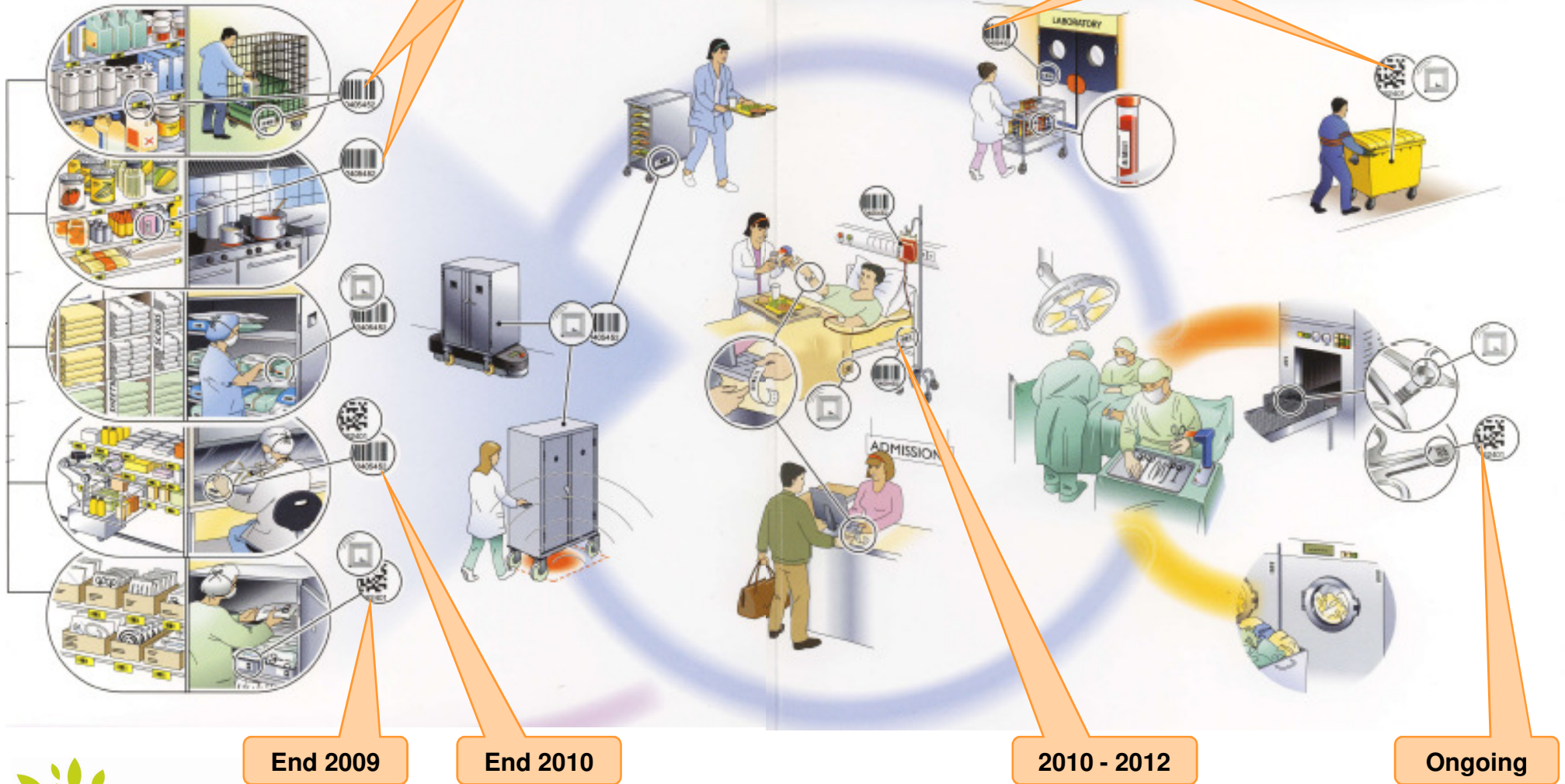
- First results show the easiness of the logistic of tagging
  - Laser 2D barcodes are practically all readable and it is possible to tag small instruments
- 



# Our next GS1 projects

April 2010

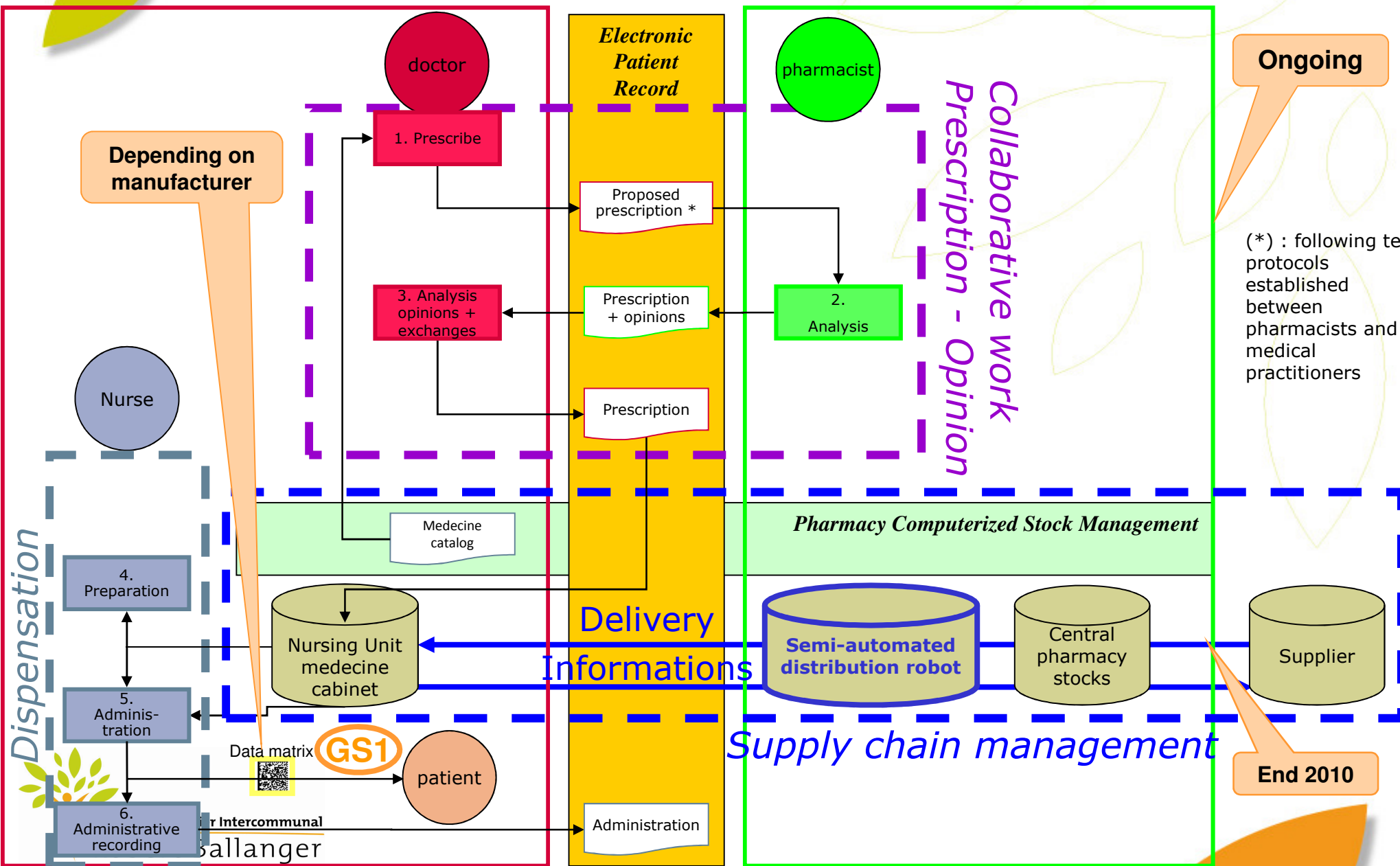
2010 - 2012



# Link between prescription and material flow (GS1) : a focus on drug process

Ward / Nursing unit

Pharmacy





# What are we all aiming for?

## Improving patient safety



- And GS1 standards are helping us ...

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