# UZ LEUVEN

## Medical software

- selection criteria

- validation before implementation

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# The lab environment



other

HIS

pre-and post-analytic automation

test request

other

HIS

billing

LIS

sample management

result reporting

print, fax

result server, medibridge, other

rule based validation software

production of validated results

analyser software

iQC software

middleware
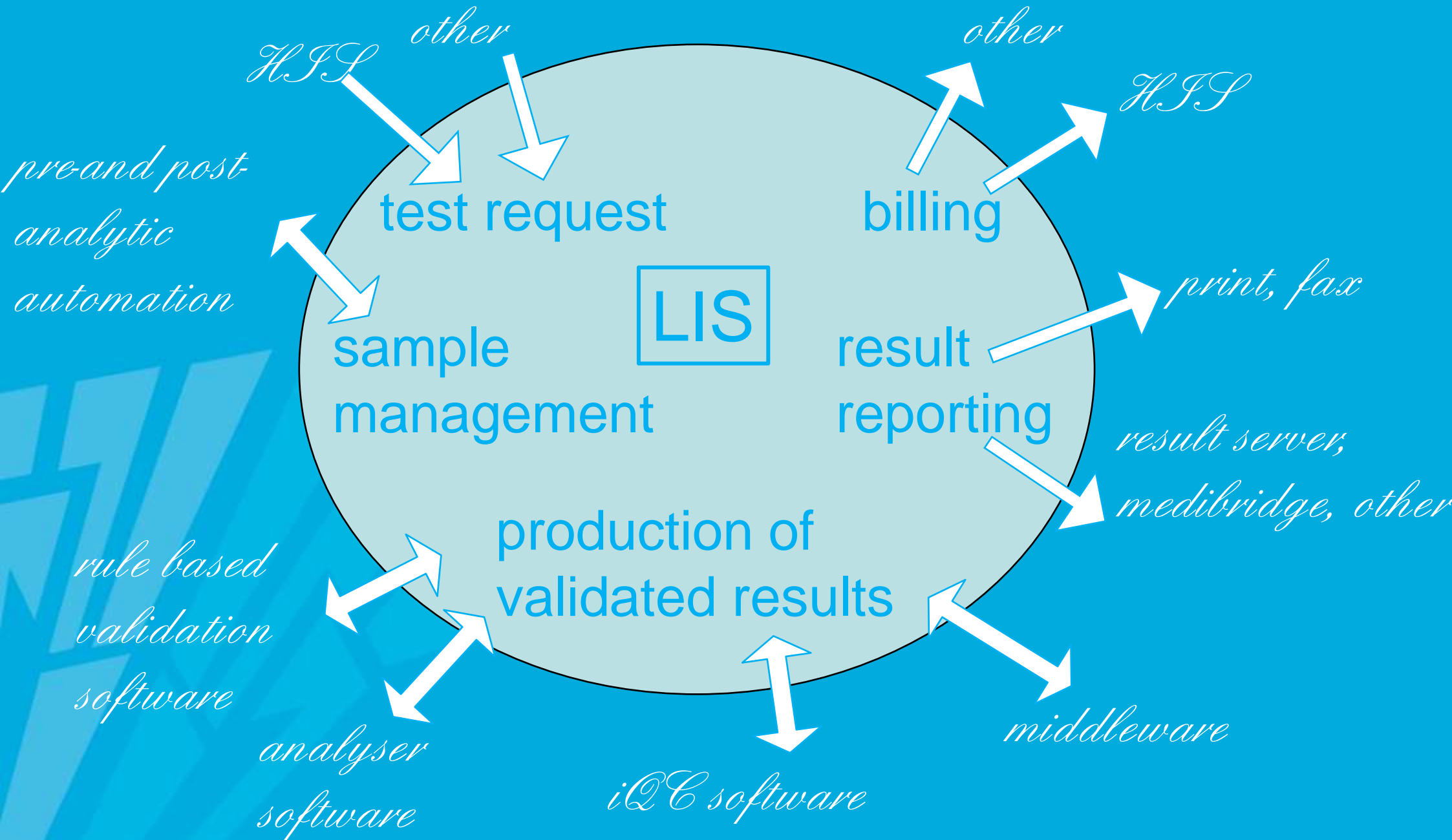
# What do we need ? Learn it from:

- the inventory of processes
  - ➥ optimize the processes
    - ➥ how can software help ?
- current software shortcomings and excessive complexity

- newly available useful tools

request for proposal

# Prior to selection: in your organization

- within one field, vendors offer similar software, none will meet all your needs
  ⇨ rank your needs in order of importance

- define where the new software will fit in your (already complex ?) software network

- focus on people
  - another extra software: learning curve !
  - resources for parametrisation available ?

# Prior to selection: with vendors

- travel ! have a look at different sites
  - ⇨ the end result is a function of both
    - the software
    - the user defined parametrisation
- request for clarification for all items in the proposals that are too vague

# Criteria for selection

- must meet your most important needs

- choose for the least complex system that does so

- avoid black boxes, go for transparency

- and of course:
    - at an affordable price (include maintenance)
    - to be delivered within a reasonable timeframe

# Criteria for selection

*e.g. analyser or pre-analytical automation communication software*

- *uses standard communication protocols (ASTM, HL7) ⇨ specs must be included*

- *preferably host query*
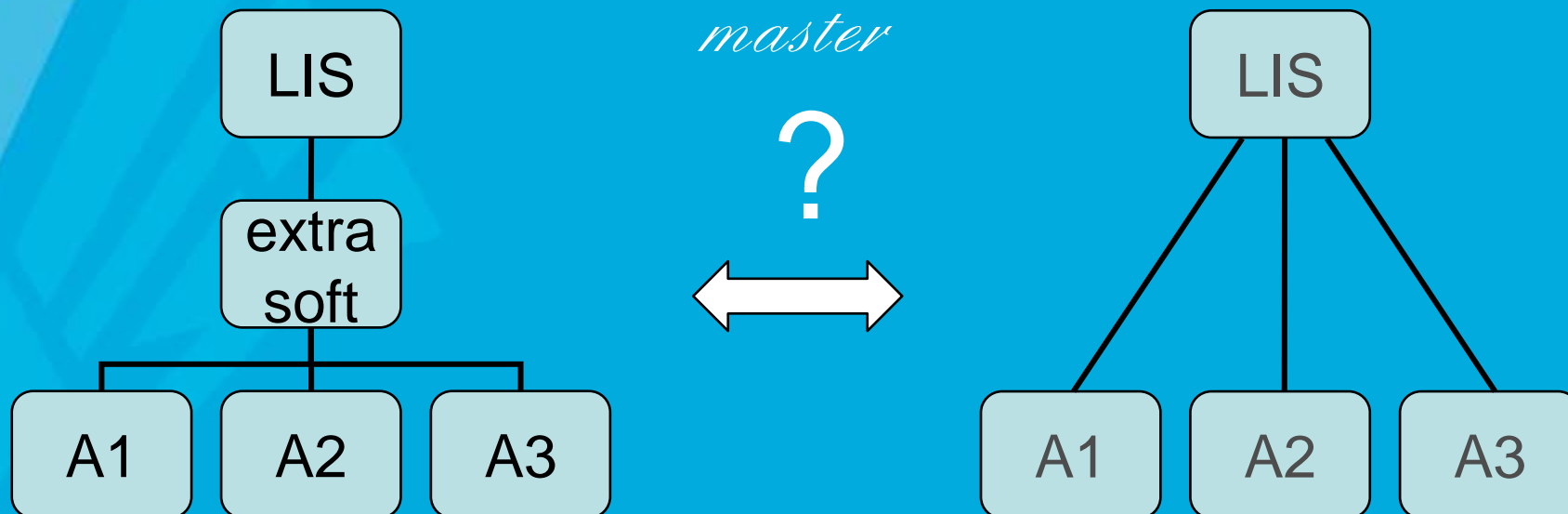
# To do's before signing the contract

- talk to the vendor (IT to IT staff) about
  - connection to the organization's network
  - remote access for the vendor & protection of patient data
  - clarification on the communication protocol
  - hardware requirements
  - organization and vendor's responsibilities

- make the above consent part of the contract and define the consequences when not met

# Validation of software

- prepare a validation plan

- perform testing (and document!)

- analyze and handle the errors

- evaluate the results

- come to a final approval and go/no-go decision

# Validation plan consists of:

- resource requirements (personnel, materials) and timeline

- description of the intended performance of the software and its interactions with other applications

- detailed test procedures to certify this performance
  - normal, boundary, invalid or special case, parallel, stress, ... testing)
  - who ?, when ?, pass-fail ?, ...

- acceptance criteria

# Detailed test procedure
## e.g. LIS new version

- perform the standard testing procedure
  - from request to report for different types of lab tests
  - all other applications (sample management, …)
  - user defined calculations, alerts, …

- test all new functionalities / bug corrections

- collect all printed material (labels, reports,…)

- if necessary improve the manual and notify the users

- if OK move test version to production

# Test procedure: checklist

**Checklist:·Java·KWS·runtime¤**

| JKWS·versie:↵ | ☐·JKWS·Test¶ |
| | ☐·JKWS·Try¶ |
| | ¶ |
| | ___·/·___·/·200.·___·:·___¤ |
| **Datum·uitvoer:**¤ | ___·/·___·/·200.·¤ |
| **Uitgevoerd·door:·**¤ | ☐·lissupport-lid·1¶ |
| | ☐·lissupport-lid·2¶ |
| | ☐·lissupport-lid·3¶ |
| | ☐·lissupport-lid·4¶ |
| | ☐·lissupport-lid·5¤ |

**1.·Aanvragen·**¤

**A.··Testen·van·aanvraagmechanisme**¤

Selecteer·Testpatiënt·LABO,·afd·ABD,·in·het· aanwezigheidsbeeld·van·eenheid·0.¤
Via·Lab·aanvraag·–·Labo·aanvragen·–·Vraag·aan:¤
4431·+·4402·+·4435·+·4042·+·4043·+·4044·+·4001¤
4003·+·4004¤

**P·☐·** ⇨→3·etiketten·¤

Selecteer·Testpatiënt·Zwitsal,·afd·MAT,·in·het·

# Test procedure: report

## VERSLAG·TESTEN·LIS·RUNTIME¶

- **TESTEN·LIS·RUNTIME·NR.·322** → ¶
- **DATUM·PRODUCTIE: DD/MM/JJJJ**¶
- **UITGEVOERD·DOOR: VP·=·NAAM·LISSUPPORT·UITVOERDER**¶
- **UPDATE·LIS-HANDLEIDING: ·**¶

  - → Voor volgende specifieke punten: **Recente validaties**¶
  - → Update uitgevoerd door: **RG= naam lissuppor uitvoerder**¶

¶
¶
- SPECIFIEKE· PUNTEN· VOOR· DEZE· RUNTIME· (PROLOG)¶

(Het· is· de· bedoeling· hierna· kort· weer· te· geven· welke· nieuwigheden· in· deze· runtime· zitten, ↵
·:· je· kan· bijv.· de· mails· van· Labocel· hierna· kopiëren.)¶

| ¤ | Verandering·/·Probleem¤ | ¤ | Wie?¤ | ¤ |
|---|---|---|---|---|
| 1¤ | Deze versie bevat volgende wijzigingen:·" implis] [Recente validaties] Herschikking van de kolommen en herformatering van de output. ↵ Het eadnr werd opgenomen in de resultatenlijst. ↵ De eenheid verwijst nu naar de eenheid waar de patient zich op dit moment bevindt.º Indien er geen eenheid gevonden wordt, wordt de eenheid van het voorschrift getoond.↵ Dit geldt voor de optie 'Recente validaties' en de optie 'Recente validaties (multi)'·"·(CP·(labocel),·05-05-2007)¤ | OK¤ | PD¶ +¶ LS¤ | ¤ |

# Testing pitfalls

- you search for (and will find) the problems you expect…

- it's impossible to test all imaginable combinations of events

- you look for programming bugs, but maybe user defined calculations, alerts etc are worse ???
  - zero
  - unknown
  - order of arguments
  - …

# Testing pitfalls : user 'programming'

| | A | B | C | D |
|---|---|---|---|---|
| 1 | | | =ALS(A2=1; A2+B2;ALS(A2=2; A2+B2; A2*B2)) | =ALS(A2=1; A2+B2;ALS(A2=2; A2+B2; A2*B2))+B2*2 |
| 2 | 1 | 2 | 3 | 7 |
| 3 | 2 | 3 | 5 | 11 |
| 4 | 3 | 1 | 3 | 5 |
| 5 | 1 | | 1 | 1 |
| 6 | | 3 | 0 | 6 |
| 7 | 4 | | 0 | 0 |

programmatieProblemen.xls  [Compatibiliteitsmodus]

# Testing pitfalls : user 'programming'

| | A | B | C |
|---|---|---|---|
| 1 | | =ALS(A2>3;"sterk positief"; ALS(A2>2;"matig positief"; ALS(A2>1;"twijfelachtig"; "negatief"))) | =ALS(A2>3;"sterk positief"; ALS(A2>1;"twijfelachtig"; ALS(A2>2;"matig positief"; "negatief"))) |
| 2 | 5 | sterk positief | sterk positief |
| 3 | 3 | matig positief | twijfelachtig |
| 4 | 2 | twijfelachtig | twijfelachtig |
| 5 | 1 | negatief | negatief |
| 6 | | negatief | negatief |
| 7 | 0 | negatief | negatief |

programmatieProblemen.xls [Compatibiliteitsmodus]

# When starting up production

- implement security procedures: access, audit trails

- organize training

- install incident reporting system with subsequent corrective action
  ⇨ retest

- stimulate value adding change requests
  ⇨ retest

# Conclusions

- *Selection:*
  - *start from 'what do we need ?'*
  - *situate in context: KISS !*
  - *good agreements make good friends*

- Validation:
  - prepare a plan
  - act upon it
  - be careful with the testing pitfalls