



economie

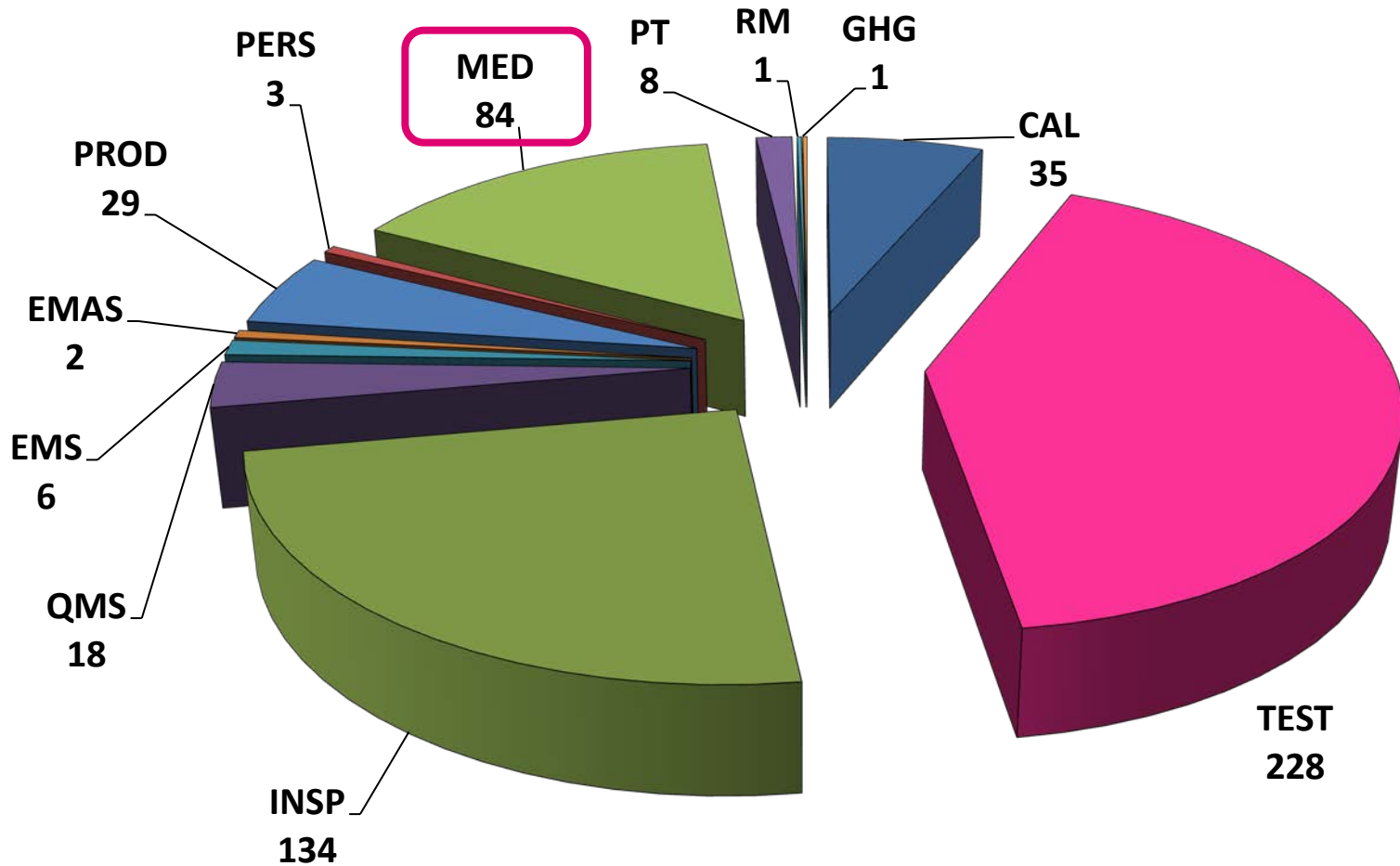
FOD Economie, K.M.O., Middenstand en Energie

Accreditation of NGS within ISO 15189

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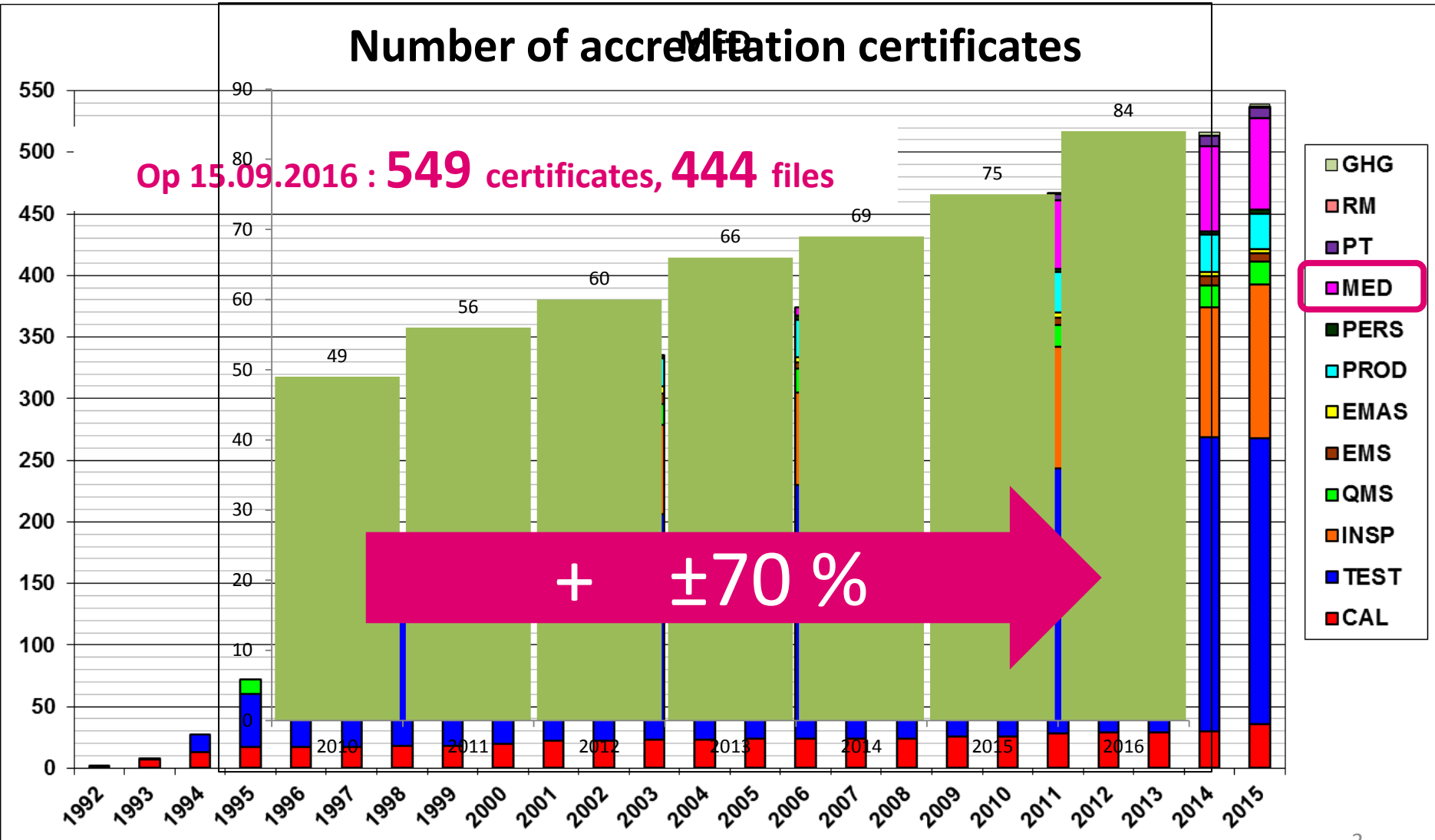
Number of certificates 2016 (549) (20.09.2016)



Number of accreditation certificates

Op 15.09.2016 : 549 certificates, 444 files

+ ±70 %



- NGS in scope → 15 laboratories (9 N / 6 F) + 2 applications (extension of scope)
- Different platforms used in oncology and hemato-oncology



- **NGS audit: clinical biology + bio-informatics**
- **Increasing demand for extension of scopes with NGS technique**
- **Questions concerning the accreditation of NGS consortia/networks**
 - different levels: post-analysis, equipment, cross border, ...
- **Contact BELAC to discuss possibilities in advance**

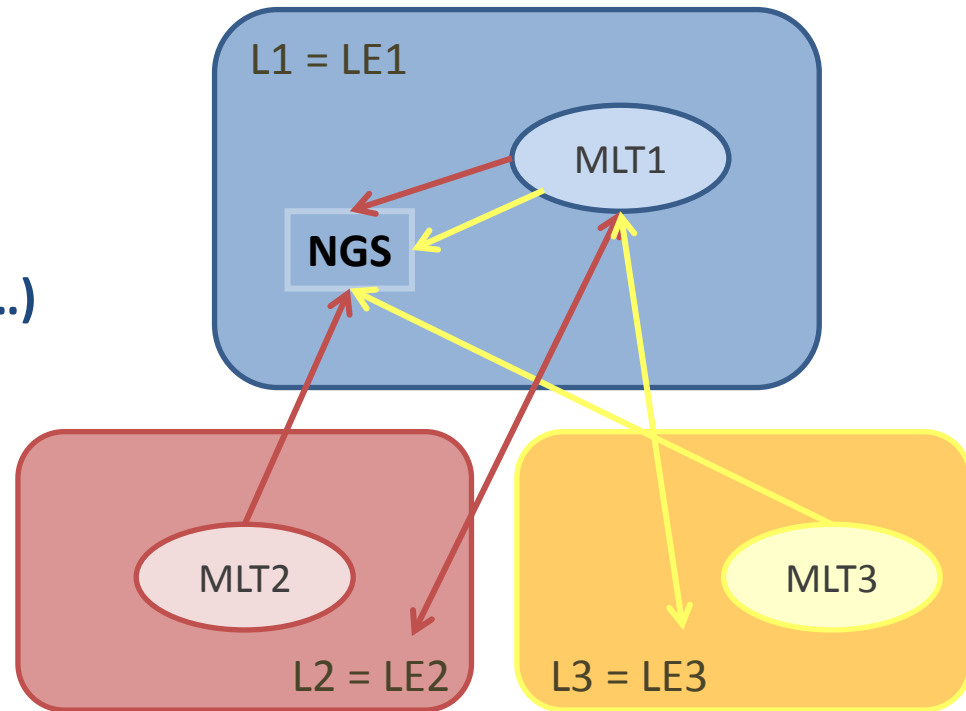
1° Sharing of NGS equipment/personnel

Situation:

- NGS equipment is property of lab 1
- Lab 2, 3, ... make use of this equipment
- Multiple legal entities (QS1, QS2, QS3, ...)

Prerequisites :

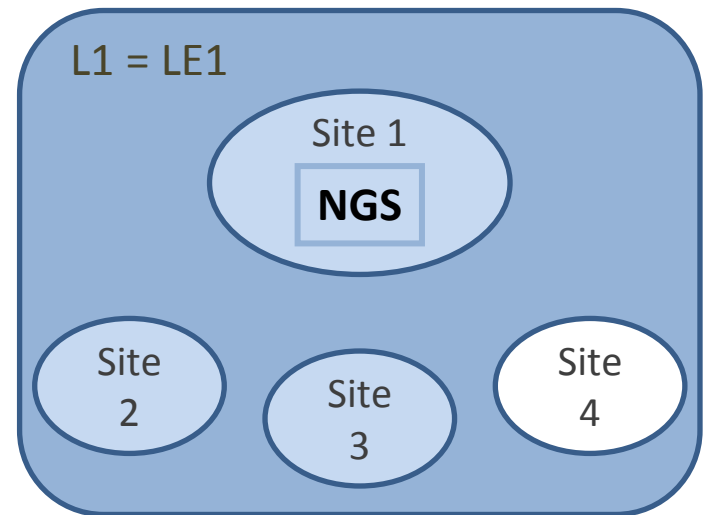
- trained personnel
 - MLT2, 3, ... use NGS in QS2, QS3, ...
 - OR MLT1 working for QS2, 3, ...
- equipment is fit for purpose = it suits for tests of lab 1, 2, 3, ...
 - check before use
 - common NGS management



2° Multisite accreditation for NGS equipment

Situation:

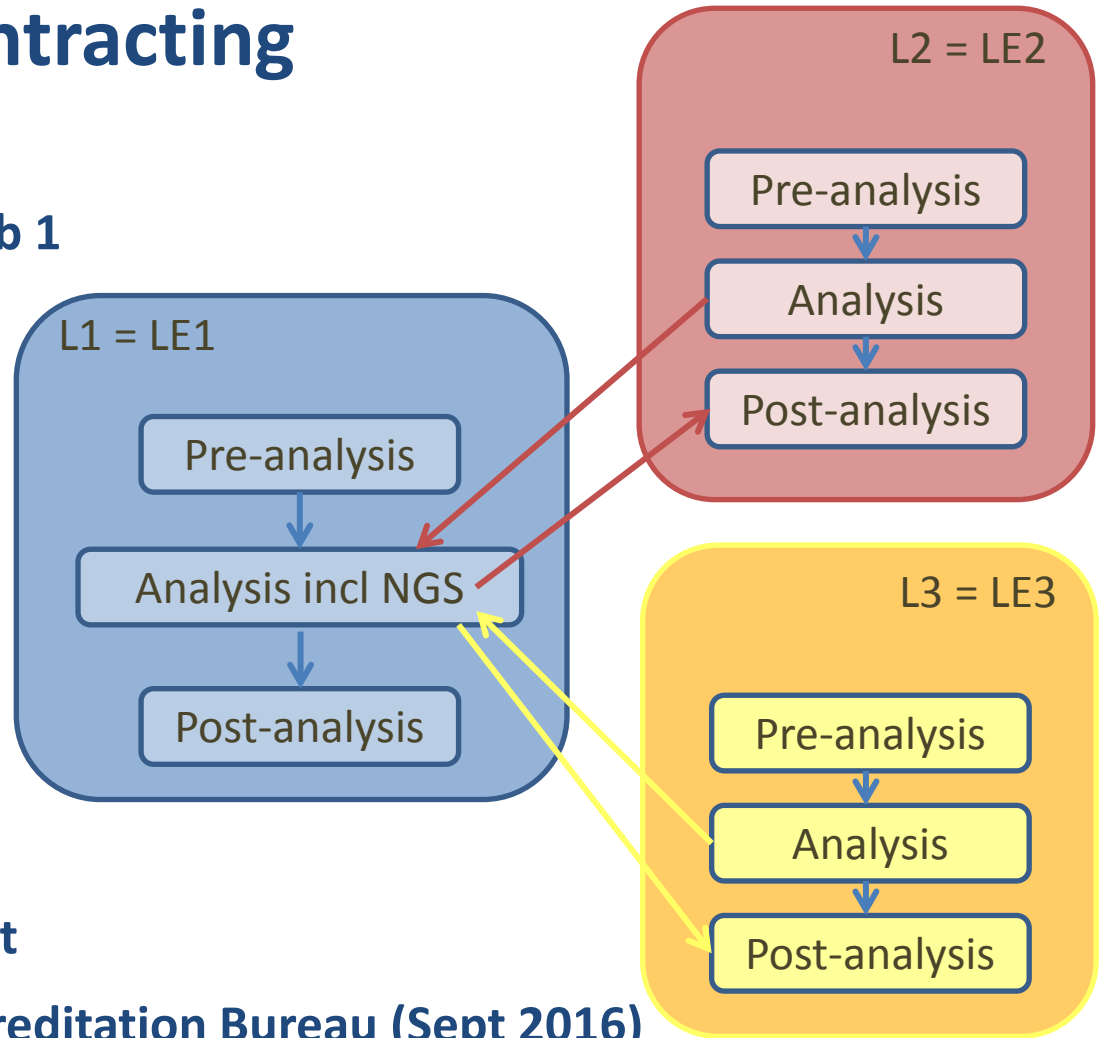
- NGS equipment is located @ site 1
- Only 1 legal entity = 1 QS
- Multiple sites



3° Continuous subcontracting

Situation:

- NGS equipment is property of lab 1
- Multiple legal entities
- Subcontracting of NGS equipment in QS1
- Personnel of L1 in QS1



Exception on Belac 1-03 document

Agreement of the concept by Accreditation Bureau (Sept 2016)

→ Prerequisites

Prerequisites to be met in case of continuous subcontracting

- Both laboratories concerned are accredited for ISO 15189
- Exception only approved for the NGS technique or part of it
- Both laboratories concerned have implemented NGS guidelines as published by “Het kankercentrum”
- Only valid for NGS in the field of oncology and hemato-oncology

Key elements to be provided in advance

- Reasons for subcontracting
- Responsibilities (including data-analysis and medical validation)
- Sample flow
- Risk analysis
- Quality control of subcontracted part
- Percentage of subcontracted tests (total accredited tests & specific test)
- Continuous evidence of technical competence for subcontracted activities

Thanks for your attention!

Questions?

