Outcome of the EBF survey on Electronic Laboratory Notebook

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on behalf of the EBF TT 30

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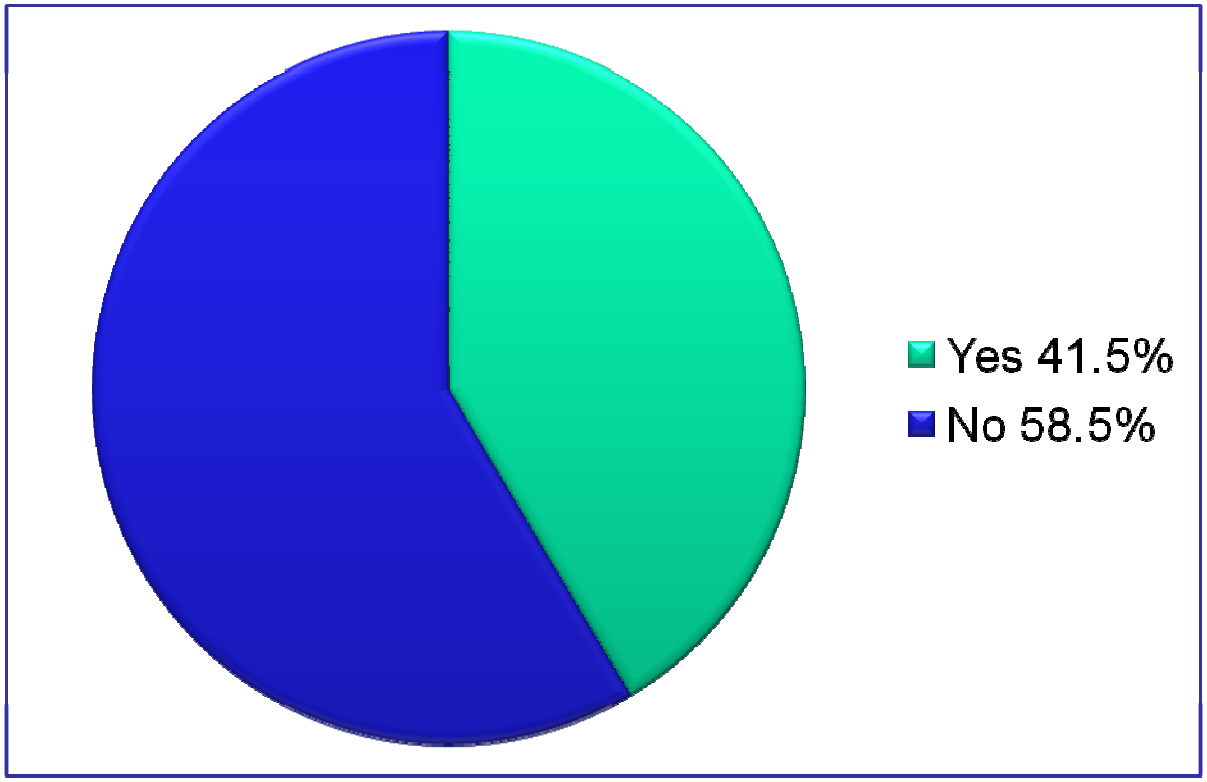
Introduction

- The aim of the survey was to learn about peoples motivation as well as hesitation to implement an ELN system in a bioanalytical laboratory, and to benefit from the experiences made.
- The first few questions applied to all EBF members, whereas subsequent questions only applied to ELN users.
- 41 members answered to the survey, of which 17 use an ELN

Do you use an ELN or are currently implementing it ?

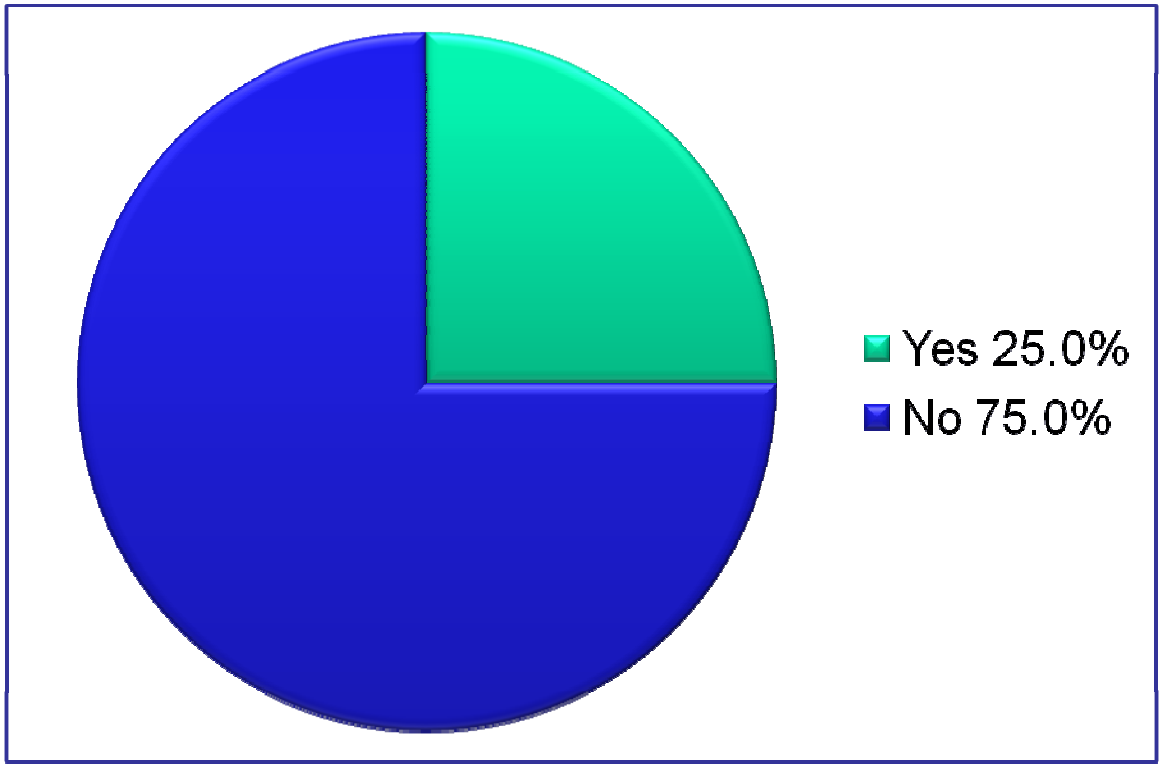


Biobook - IDBS: 3 Cambridge Soft – Perkin Elmer: 3

ECM – Agilent: 2 Labnotes – Laboratory Data Solutions: 6

Symyx - Accelrys: 2

Do you plan to implement/purchase an ELN within the next 18 months ?



No, because:

- (validation) effort (time/costs) versus benefit - 9 votes
- budget limitations – 2 votes
- no real concerns but other aspects more important - 2 votes
- LIMS covers most aspects of ELN – 1 vote

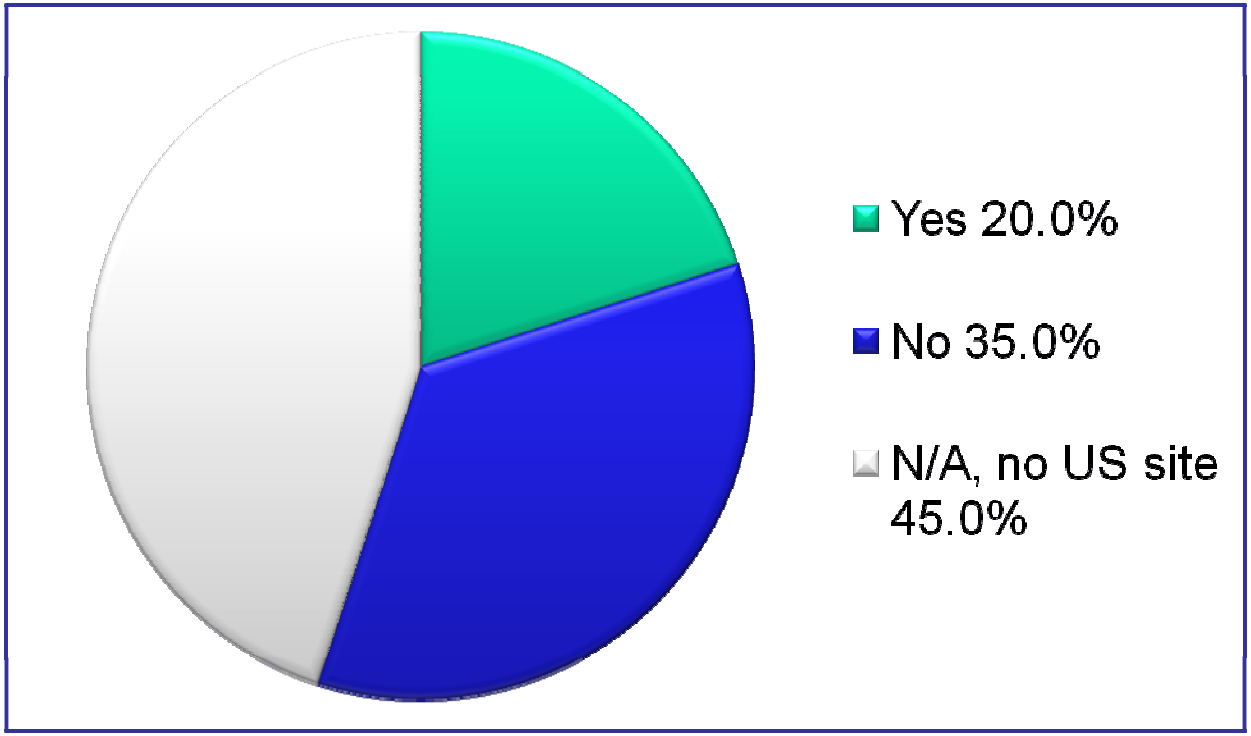
What are your concerns regarding ELN in general, if any ?

- (validation) effort (time/costs) versus benefit - majority vote
- Compatibility with existing systems (interfacing)
- Regulatory acceptance
- Doubts whether lab will be paper free
- Compatibility of laboratory procedures and software workflows

What are your concerns regarding the validation of an ELN, if any ?

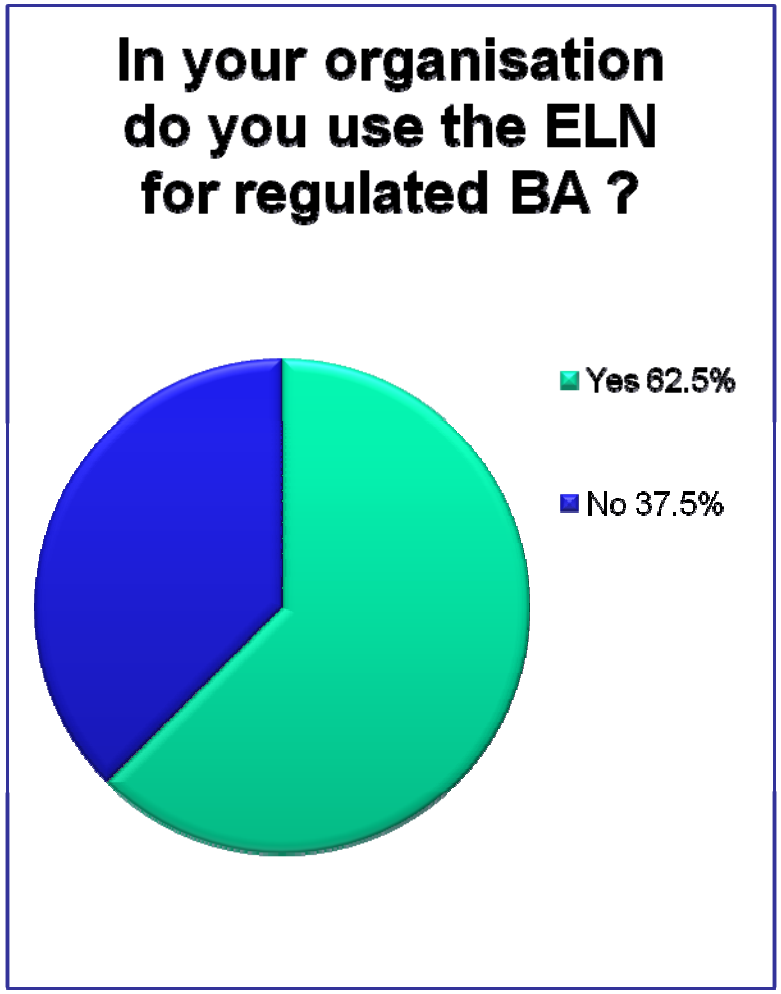
- Time and capacity needed, not only within Bioanalysis but also IT
- Effort much higher compared to analytical system
- Electronic archiving

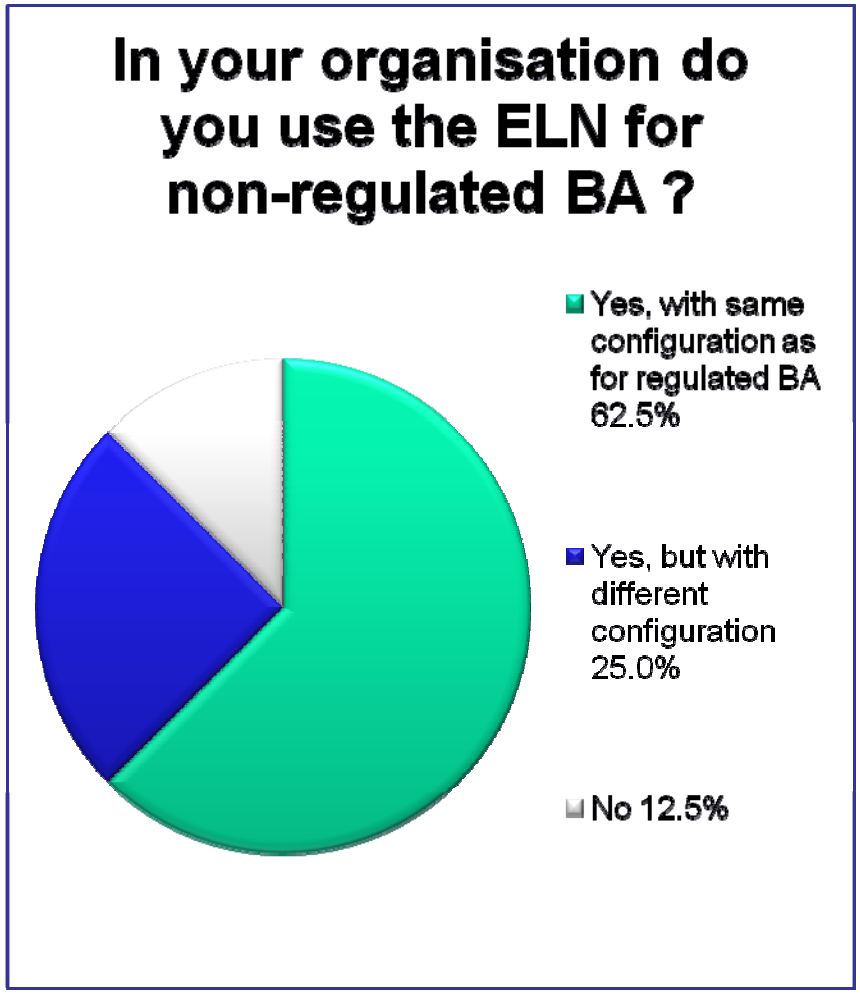
If you have a site in the US, do your colleagues in the US use an ELN system ?



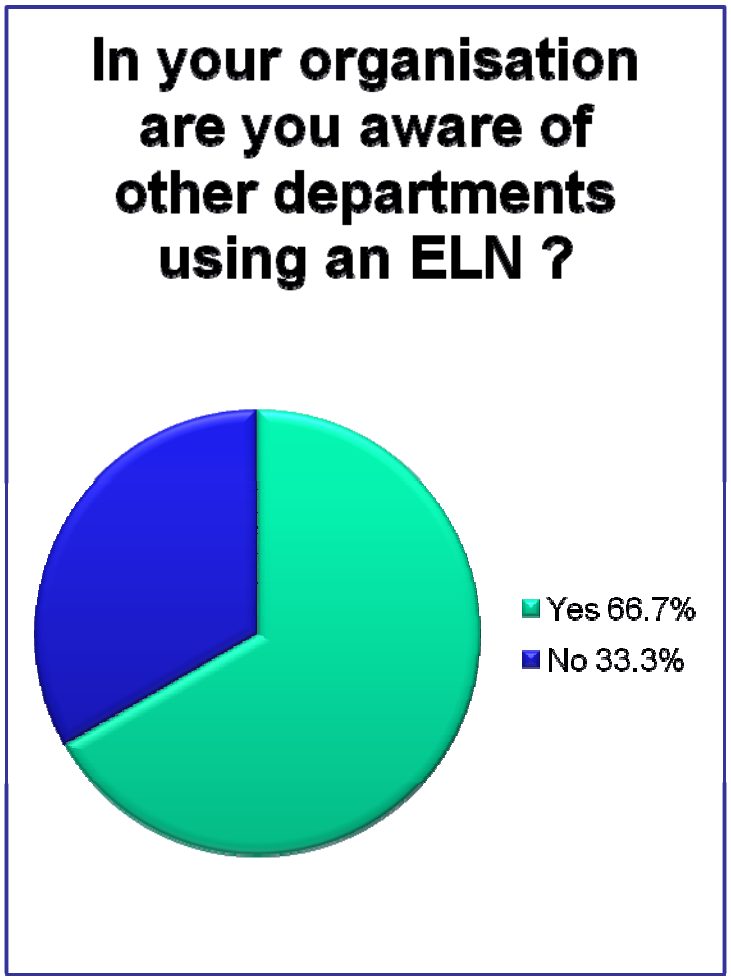
- 8 times yes
- 7 use same system as in Europe
- once ELN used at US site but not at European site

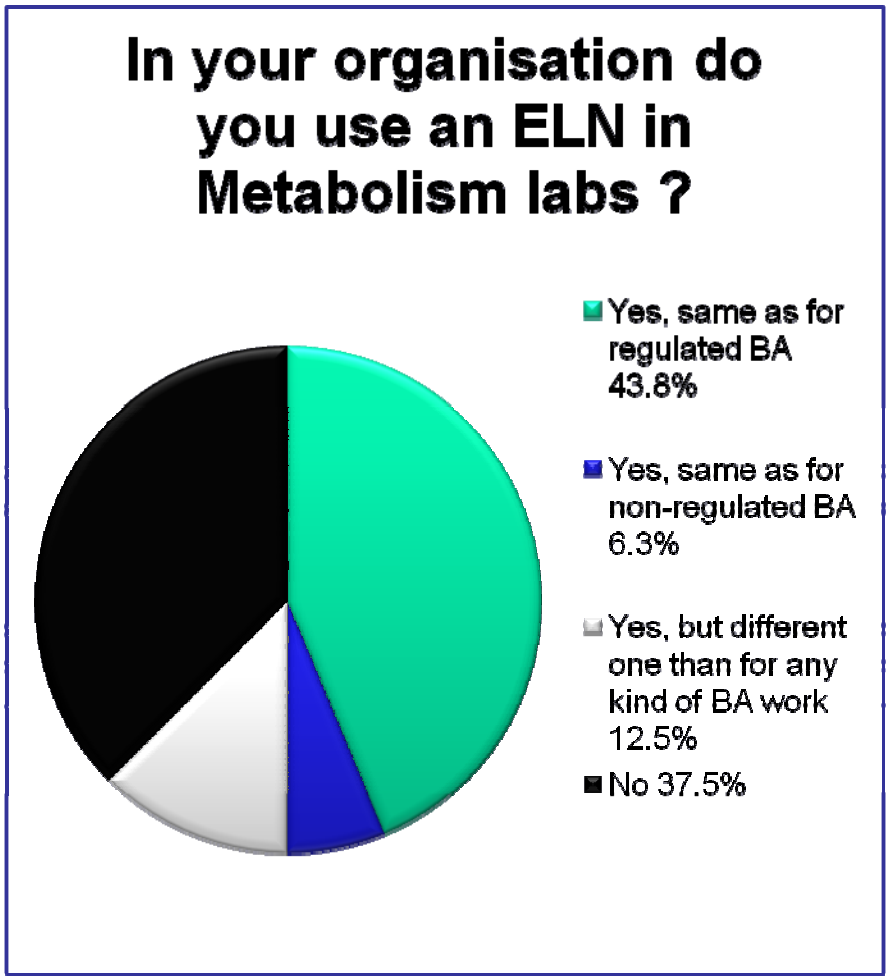
Regulated vs non-regulated



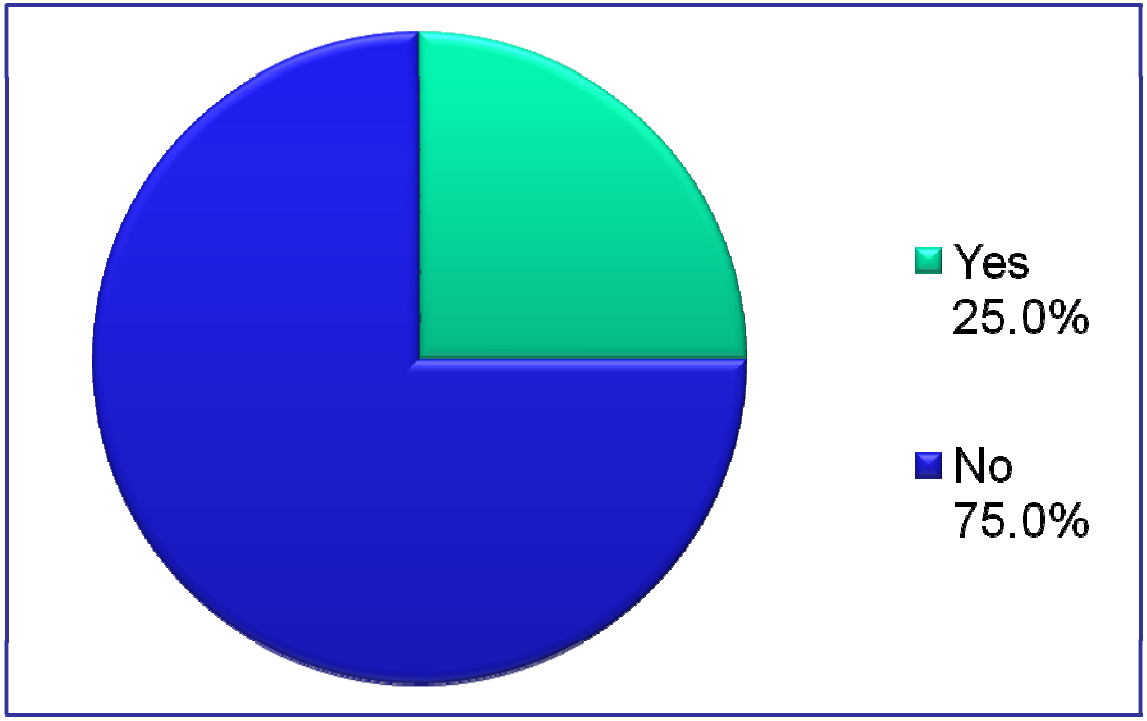


ELN in different departments



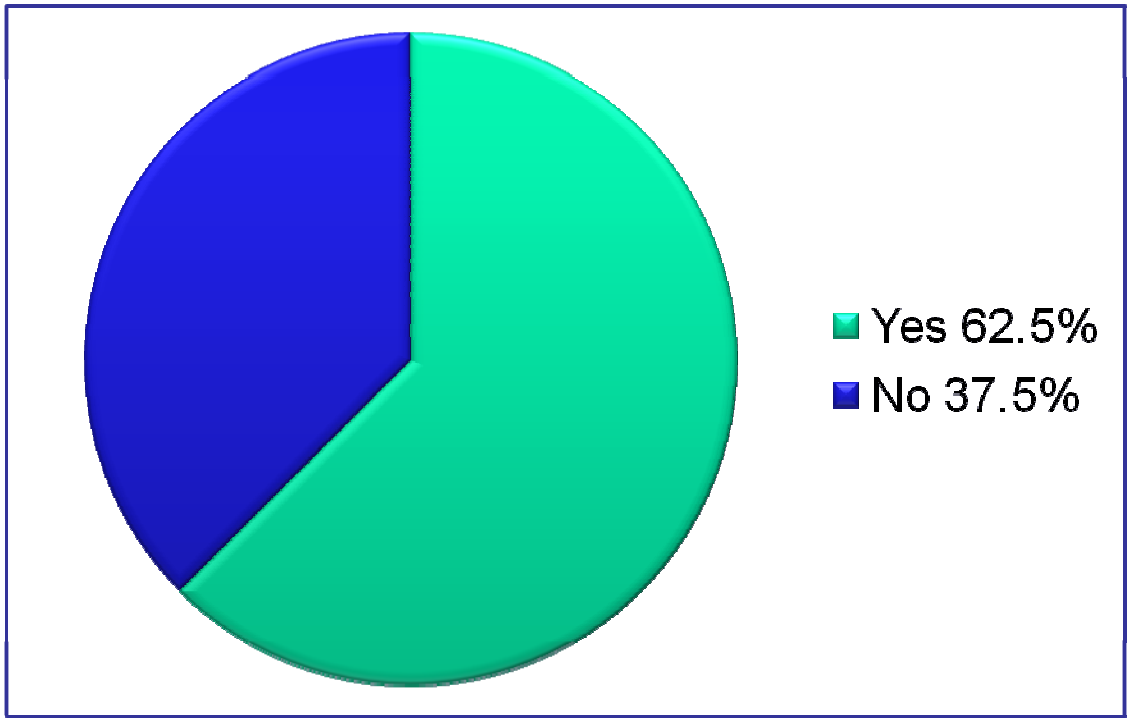


Is there a direct interface of ELN to the LIMS systems ?



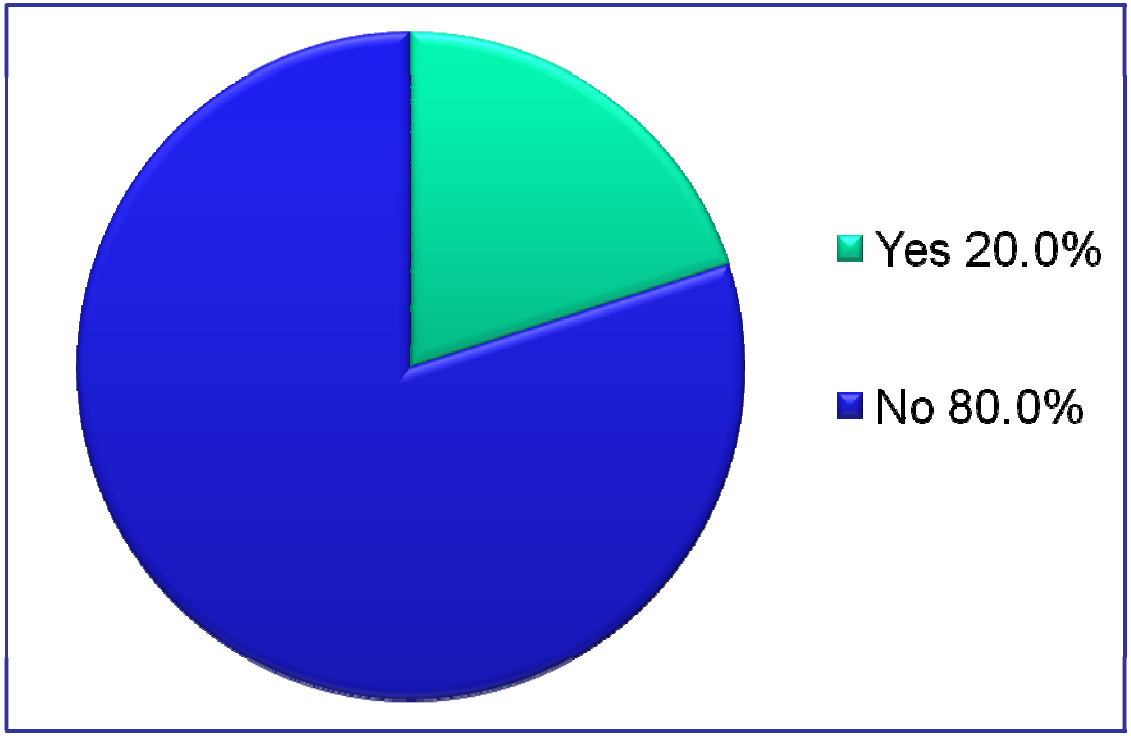
3 answers provided, 3 times Watson LIMS mentioned

Is your ELN connected to other systems than LIMS, e.g. balances, SDMS etc ?



- balances: 9
- pH meter: 4
- data repository: 3

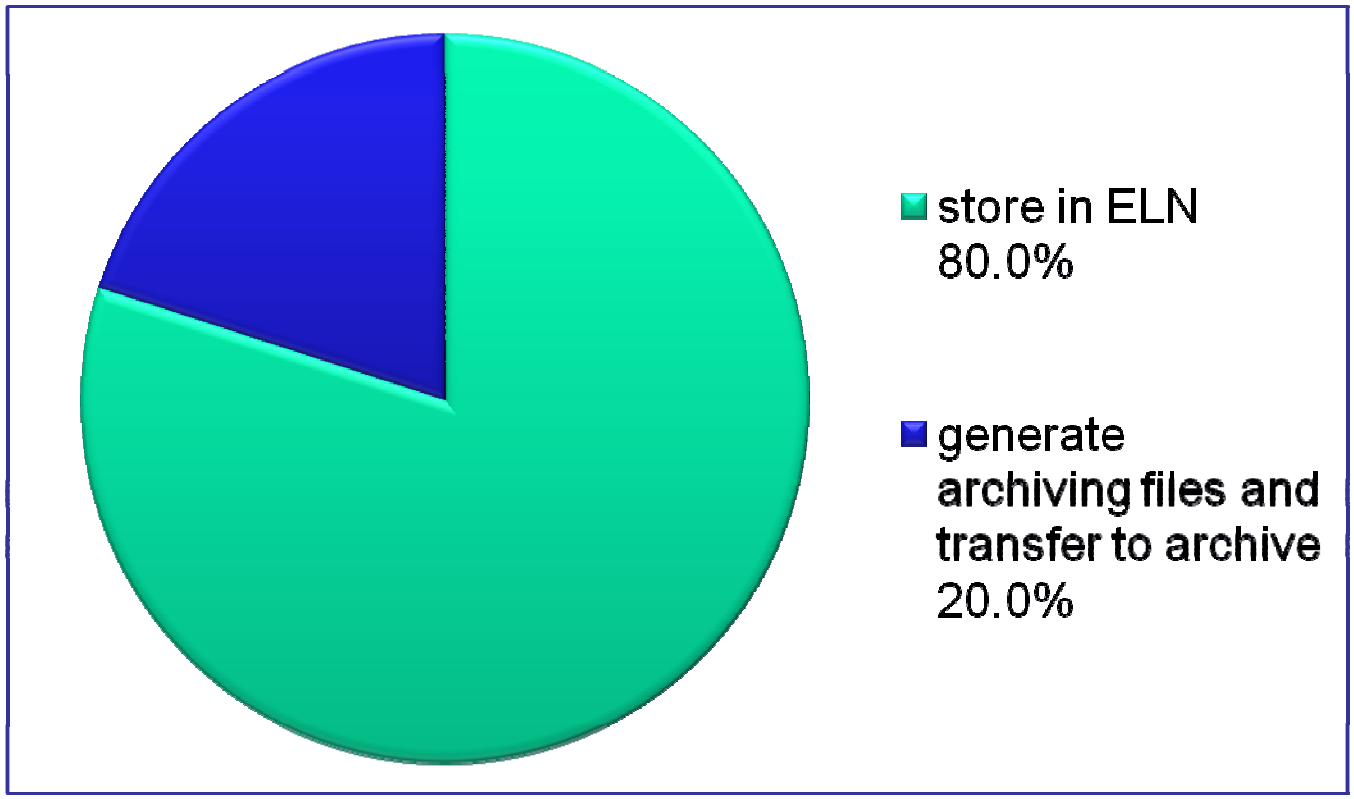
If any, do you use reporting functions of ELN?



5 answers provided:

- under evaluation/planned: 2
- tables and figures: 2, method report, exception report: 1
- consumable usage, stock reports, historical trends

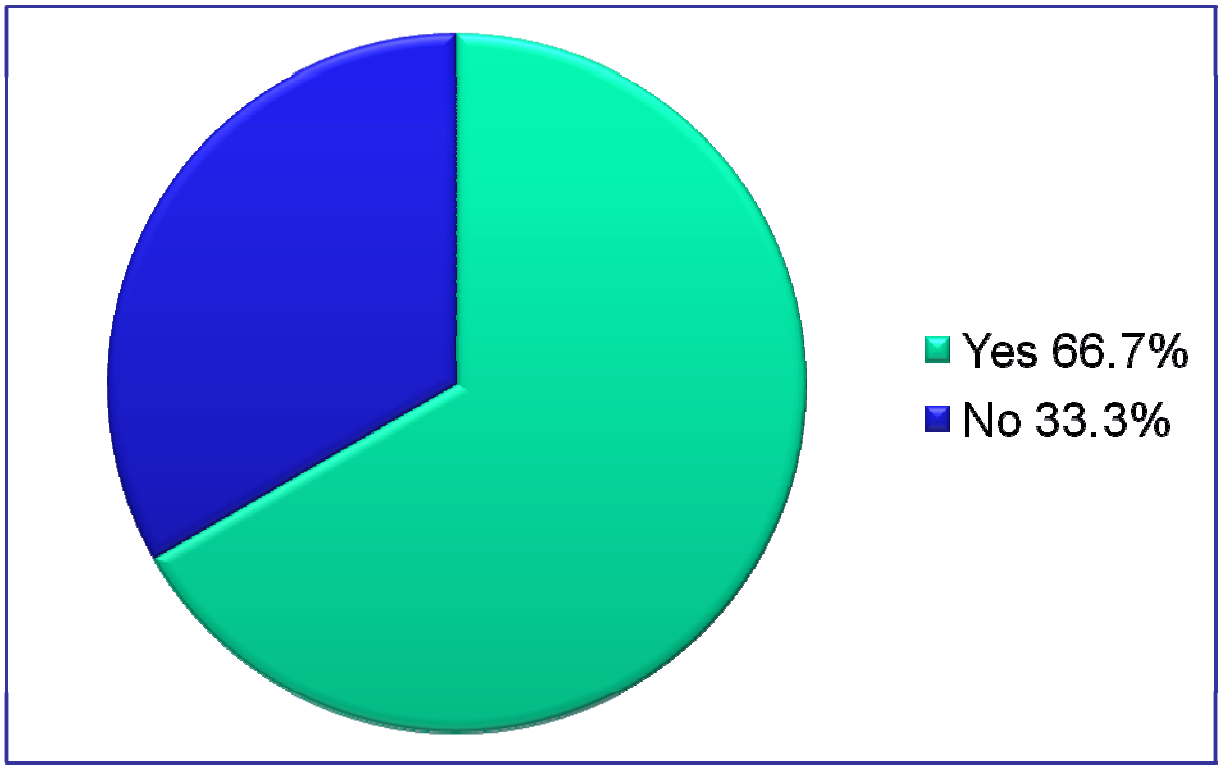
Do you store the data in the ELN or do you generate archiving files and transfer them to a GLP/GCP e-archive ?



3 answers provided:

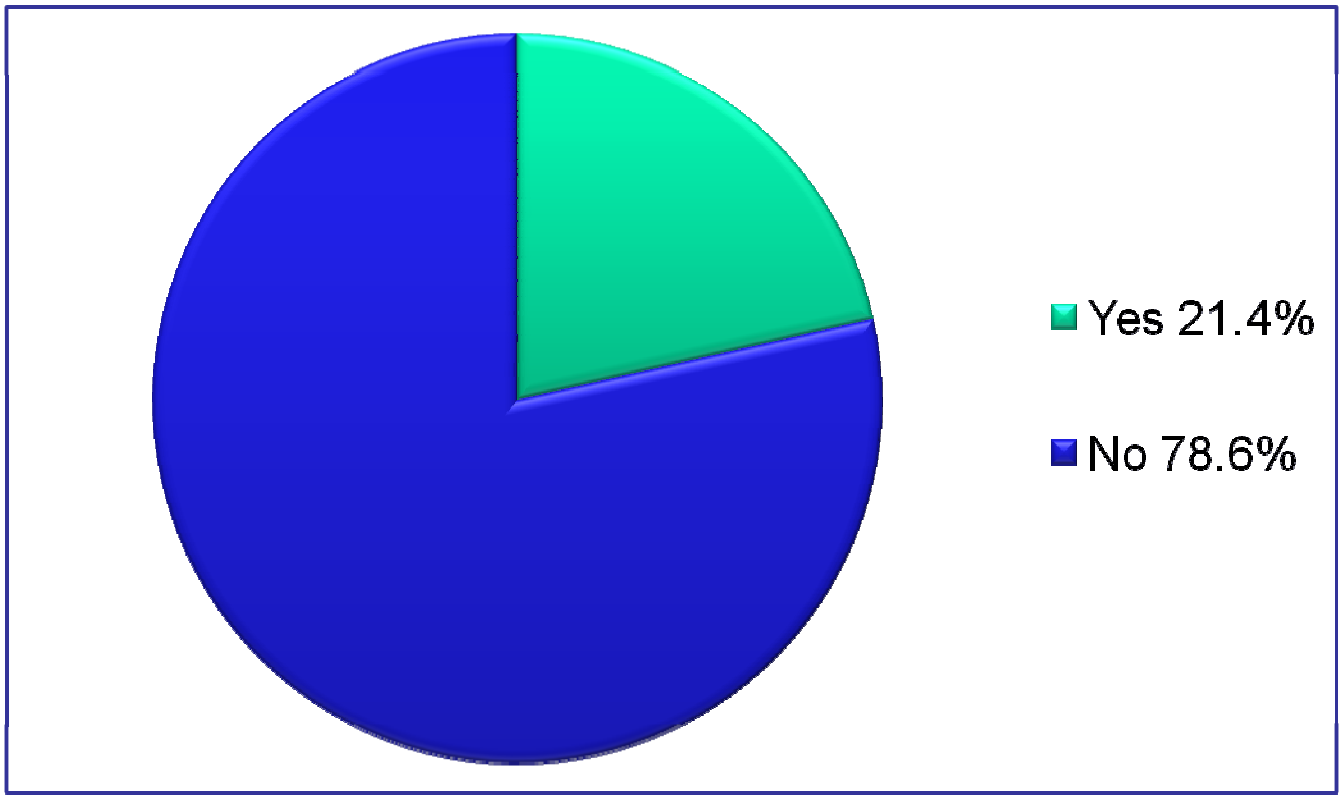
- transfer to e-archive
- transfer as PDF
- no raw data in ELN

For our CRO members: do you return ELN data to clients for archiving ?



- print to PDF format: 2
- transfer as HTML files: 1

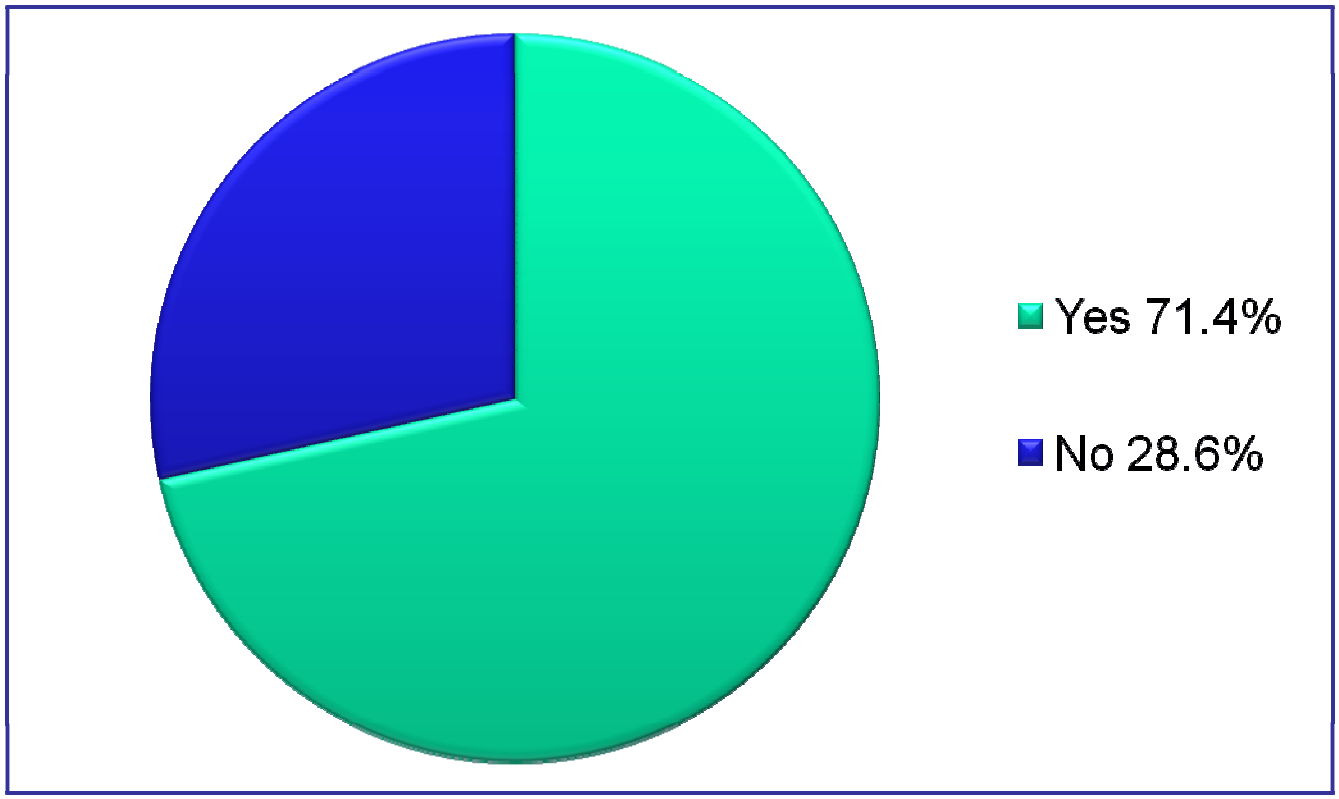
After implementing ELN is your lab now paper-free ?



12 comments received, major issues were:

- Sample shipment documentation (including import licenses)
- certificates of analysis
- fax/e-mail from external partner
- run sheets (sequence, acceptance, audit)

Does your ELN fulfill your user requirements and expectations ?

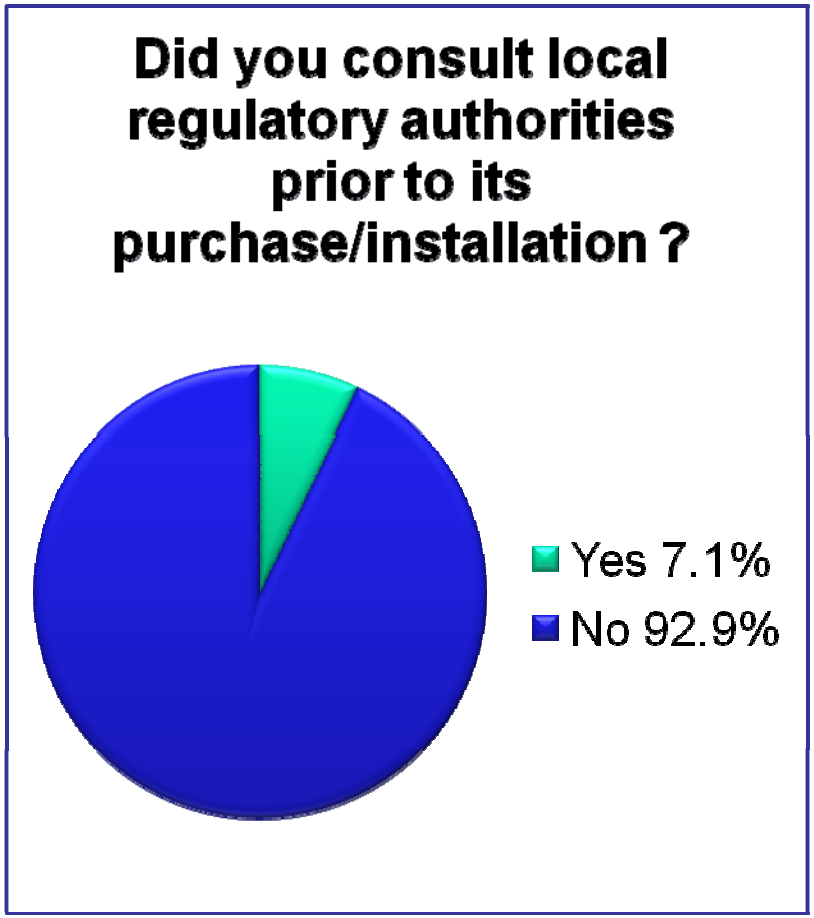


comments provided:

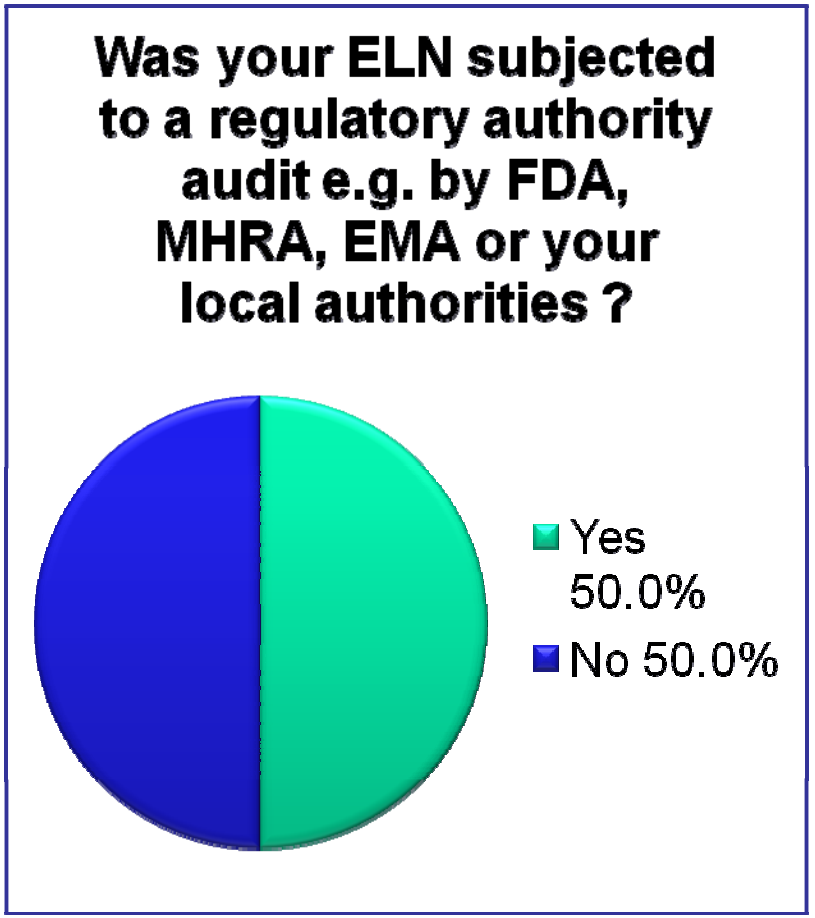
- more automation required
- more flexibility

→ Contradiction ? Different users, different requirements ?!

Regulatory Acceptance of ELN

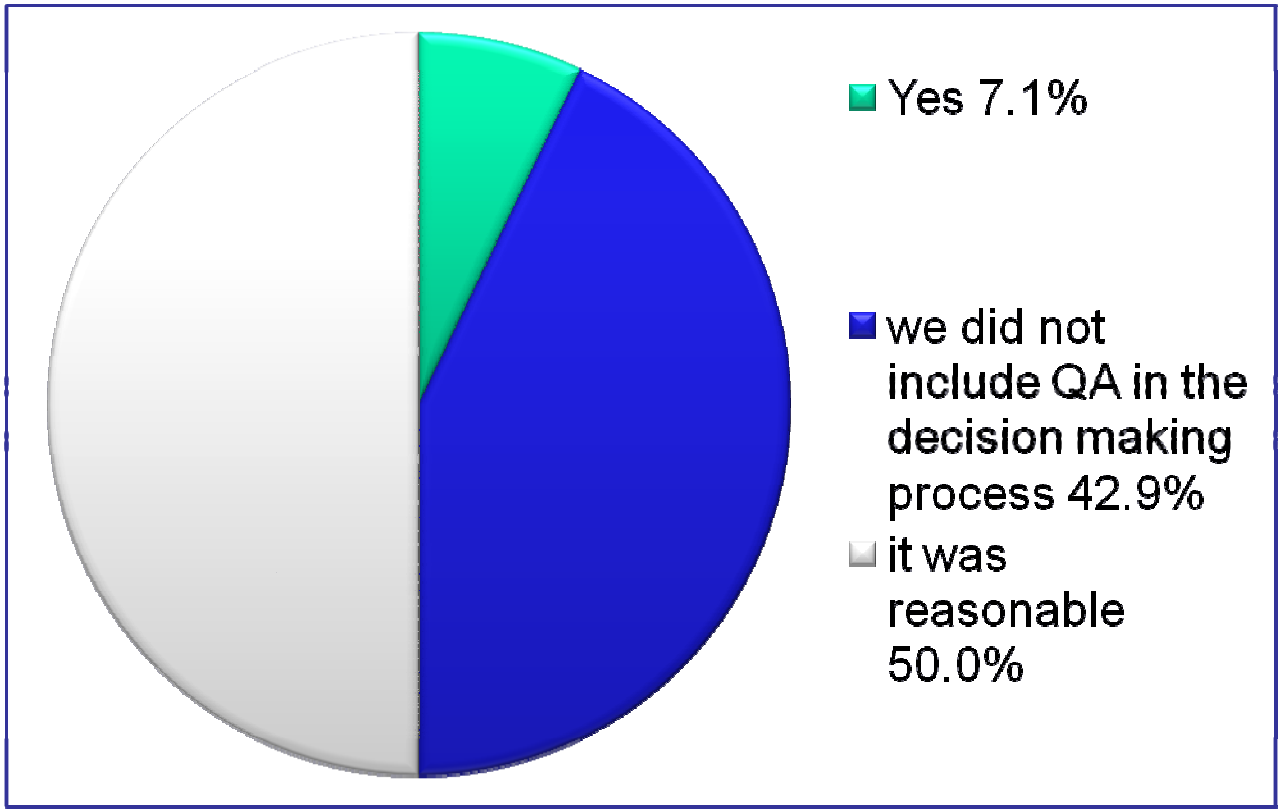


1 comment provided:
MHRA was contacted upfront but had no concerns

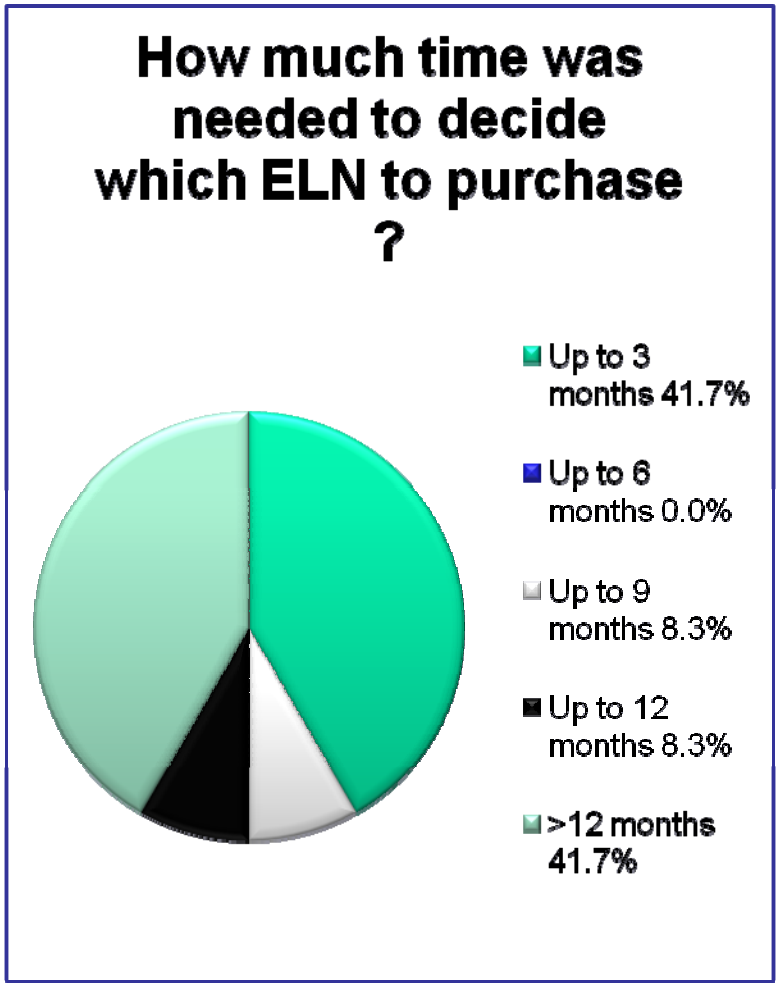


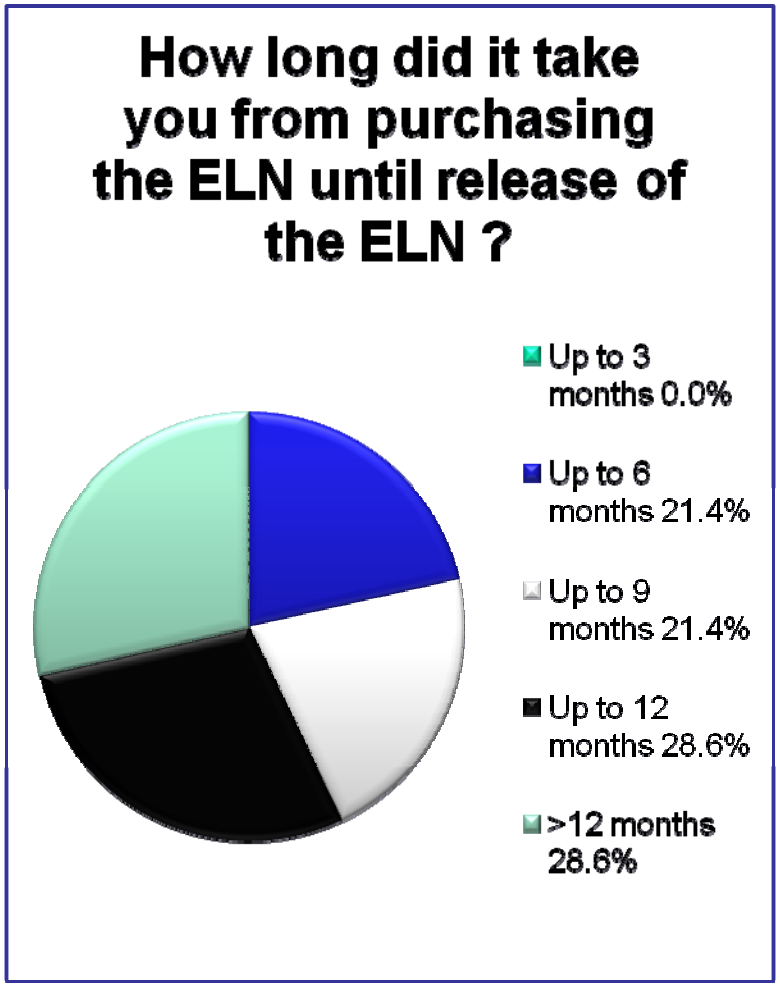
6 comments provided:
Either no issues at all, or only minor ones

Was it difficult to get your QA's agreement to the ELN ?

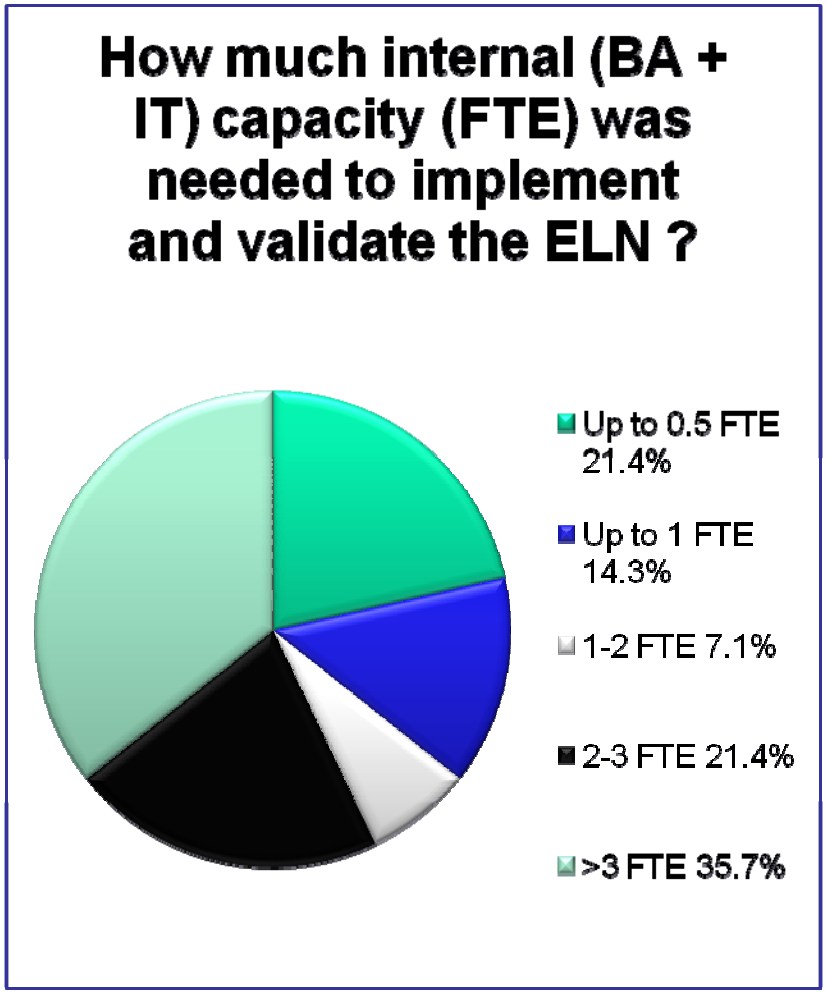


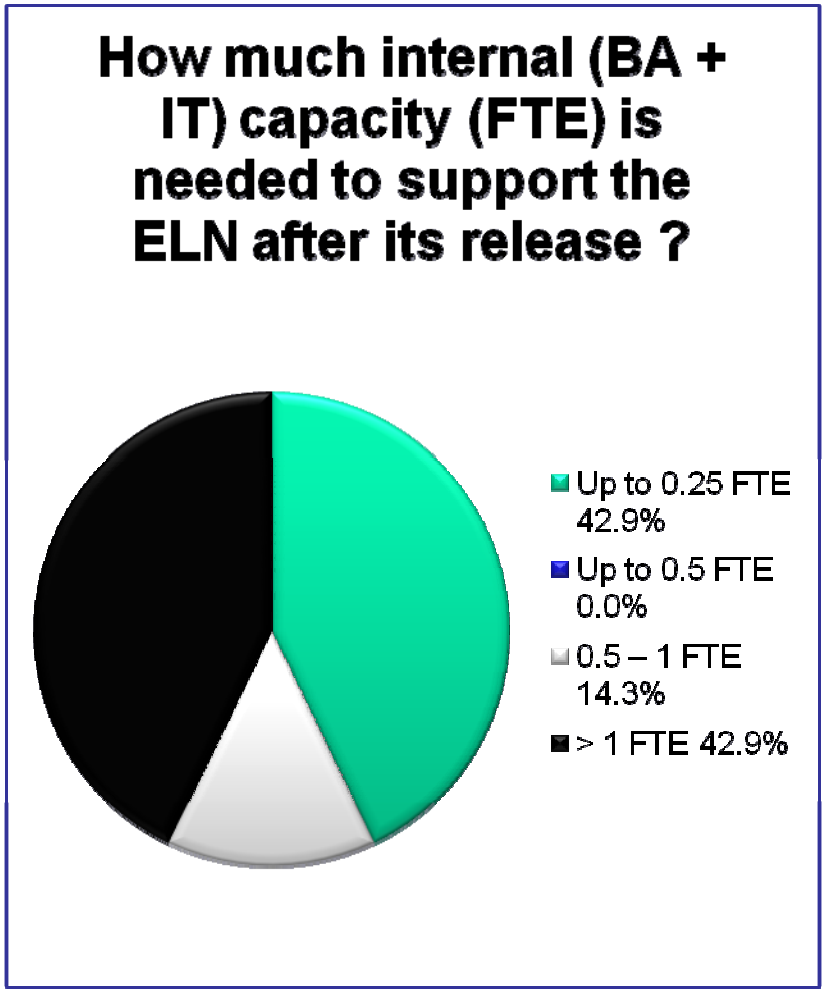
Time needed for implementation





Capacity need for implementation and maintenance





Summary

Looking at the answers provided we discovered that

- The wording of some questions was not as clear as we initially thought
- We forgot to address some important aspects
- We had some expectations, but reality proves different

The four most interesting aspects for us are:

- The benefit of an ELN versus costs/effort for implementation
- Majority of ELN users still dealing with paper in their labs
- ELN and electronic archive
- Reporting functions and data transfer options, e.g. to exchange “data” between CRO and client

Acknowledgement

- **EBF Topic Team 30: Electronic Laboratory Notebook**:
  David van Bedaf (Janssen R&D), Inneke Beirnaert (Janssen R&D), Rachel Green (Quotient Bioresearch), Paul Hurley (Covance), Luc-Alexis Leuthold (Novartis), Silke Lüdtke (Boehringer Ingelheim), René Megens (Merck), Hans Mulder (Astellas), Jan van Veen (PRA Int.)

- **All EBF members**

- **And you for your interest in this workshop and your active contribution to the subsequent discussion**

Topics for discussion

benefit of an ELN
versus costs/effort

ELN but still paper
in lab

Reporting functions
in ELN

ELN and electronic
archive

and …???