

2007 Lipient Regulatory Affairs Trends Survey

SUMMARY REPORT

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BACKGROUND

The fifth annual Lipient Regulatory Affairs Trends Survey, conducted by Thomson Scientific Market Research, provides exclusive insight into the emerging and future trends of regulatory product management needs for the life science market. The survey concentrates on four key areas: Technology Usage trends, including both submission publishing software and other desktop software; Document Management System usage; Regulatory Outsourcing trends; and Regulatory trends, including use or future use of the electronic Common Technical Document (eCTD).

KEY FINDINGS

Technology Usage:

Most percentages have remained the same over the past year, possibly indicating a plateau in the adoption of new technologies. The only significant increase was in the use of digital signatures.

- Almost all (90%) of the survey respondents make regulatory submissions.
- Current use of paper and electronic submissions has remained the same since 2006, unlike the previous year, where there was a drop in the percentage of those who did paper-based submissions only, and an increase in the percentage who did both electronic and paper processes.
- In two years' time, respondents estimate they will most likely submit to the FDA via a Marketing Application, either in paper format or electronically. Marketing applications are most likely to be used in Europe, Japan, and all other global agencies.
- Two-thirds (67%) are using submission publishing software. This percentage is similar to 2006.
 - One third (36%) of those respondents not currently using software are very likely to implement submissions publishing software into their process.
- As in the previous year, the SAFE initiative has not yet taken hold in most companies surveyed: only 4% of respondents are currently addressing the SAFE initiative. However, 26% plan to implement it in the future.
- Similarly, only 9% of companies currently have technology to support the FDA Gateway, and one third (37%) plan to implement the technology in the future.
- One-quarter of respondents (26%) are currently using a digital signature process, a significant increase of 7% over the past year.
- Six in ten (58%) respondents are not currently utilizing a digital signature process for their submissions. Of those, 43% plan to implement this technology.
 - The respondents who do not plan to implement a digital signature process stated that it is not necessary for their company or industry.

Document Management:

There were generally no changes over the past year in terms of the way companies manage their regulatory documents and the perceived benefits of document management systems.

- Three-fourths (74%) of respondents currently use a document management system and 57% of them use Documentum as their primary system.
 - 35% plan to upgrade their current version, similar to 2006.
- Respondents stated control over versions of documents and ease of access to documents as the primary benefits of a document management system, similar to 2006.
- The majority of respondents (63%) use a browser-based client, Microsoft® Internet Explorer, for electronic document management.

Regulatory Operations Outsourcing:

Companies are continuing to outsource the essentials of regulatory operations — report writing, printing, and document scanning. The amount that companies outsource has also remained the same, with the exception of complete submission publishing, which has increased. Companies generally do not expect to increase the level of outsourcing in the future.

- One quarter (26%) do not outsource any of their regulatory operations.
- The following regulatory operations are outsourced by the highest percentage of respondents:
 - study report writing (28%)
 - printing (23%)
 - document scanning, e.g. case report forms (22%)
 - regulatory liaison/consultant-content (21%)
- The percent of operations currently outsourced has remained the same over the past year, with the exception of complete submission publishing, which increased from 6% to 12%.

Regulatory Trends:

The percentage of companies planning to implement new or replacement solutions has decreased over the past year, with the exception of an eCTD viewer, which has increased. Migration to eCTD appears to be imminent.

- Four in ten (44%) state that their organization plans to adopt an eCTD viewer, an increase of 12% over the past year.
- Two in ten respondents plan to adopt SPL Labeling Management (29%), PIM Labeling Management (23%), Submission Quality Management (20%) and Pharmacovigilance (18%).
- About one in ten or fewer respondents plan to adopt the HL7's Regulated Product Submission (RPS) format, EVMPD standard, SDTM standard, SPD standard, Commitment/Correspondence Management, a Regulatory Product Team/Executive Dashboard and Clinical Trial Safety Monitoring.

- For all of these areas (with the exception of Clinical Trial Safety Monitoring), the percentage of companies planning to implement new or replacement solutions has decreased over the past year.
- Three-fourths (76%) of respondents plan to migrate to the eCTD, and those planning to migrate within 3 months increased significantly from 4% to 26%.

EUROPEAN SNAPSHOT

Due to their size, European companies have generally not been able to address regulatory challenges as quickly as larger companies. They are less likely to adopt new technologies, and are more likely to outsource essential regulatory processes.

- Significantly more European respondents work in medium/small pharmaceutical companies.
- Significantly fewer Europeans currently make regulatory submissions.
- Fewer Europeans plan to implement technology that supports the SAFE initiative, as well as the FDA Gateway.
- Fewer Europeans plan to implement a digital signature process in the future.
- Fewer Europeans are using a document management system.
- Significantly more Europeans are outsourcing their printing operations and regulatory liaisons, for both format and content.
- In the next two years, fewer Europeans than non-Europeans plan to adopt HL7's Regulated Product Submission (RPS) and STDM.
 - More Europeans than non-Europeans plan to adopt EVMPD and Pharmacovigilance.

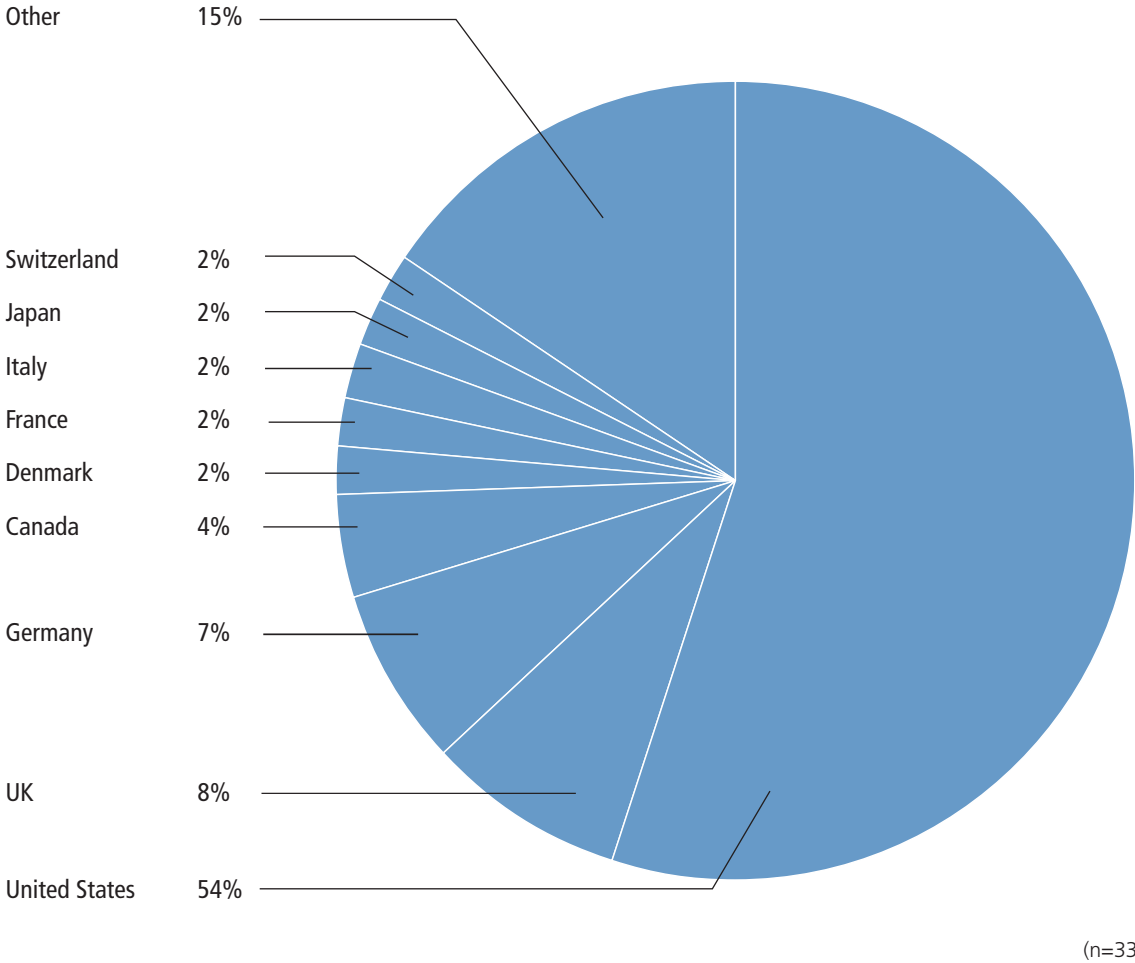
METHODOLOGY

A quantitative Web-based survey was conducted in April and May of 2007 among 338 Regulatory Affairs individuals from life science companies across the globe.

RESPONDENTS

The demographic make-up of the respondents is similar to the study conducted in 2006. Over half of the respondents are from the United States (54%). The majority of the remaining respondents are from Europe, specifically the UK (8%) and Germany (7%).

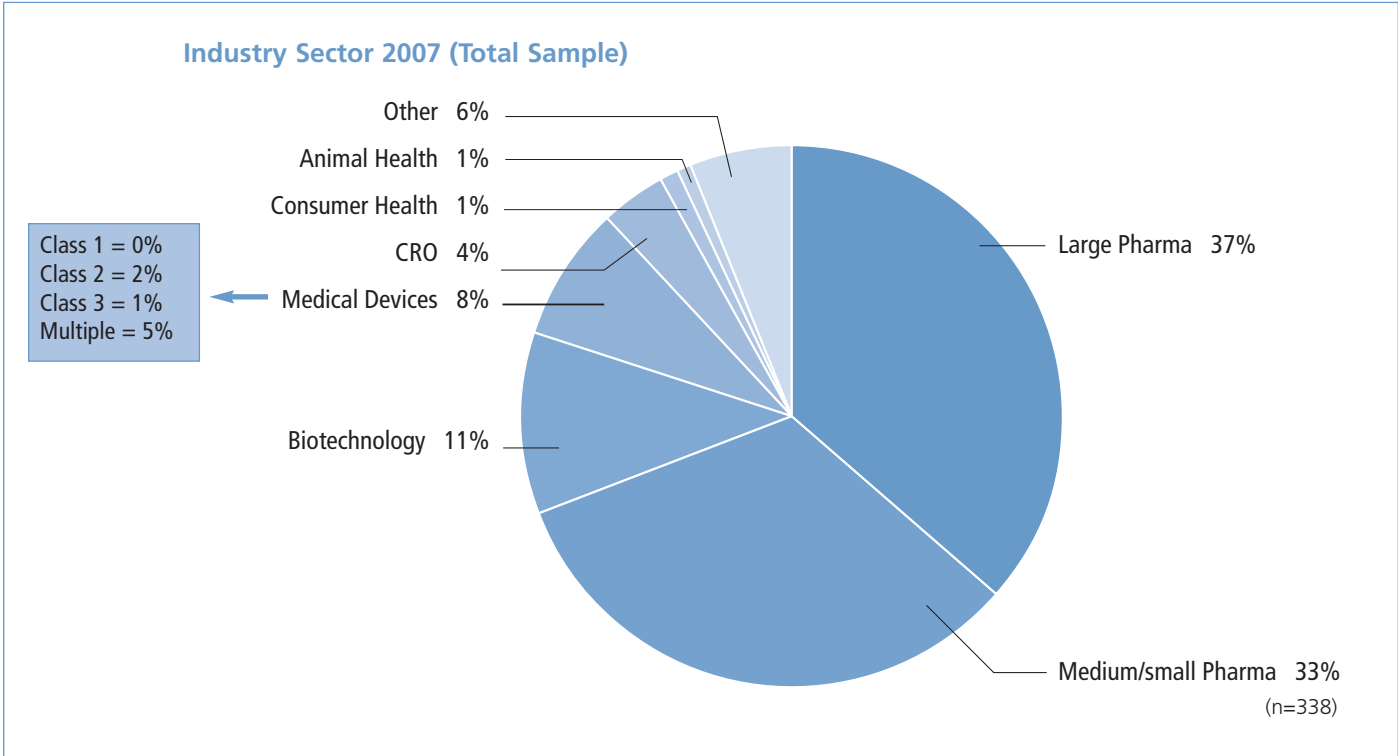
Country 2007 (Total Sample)



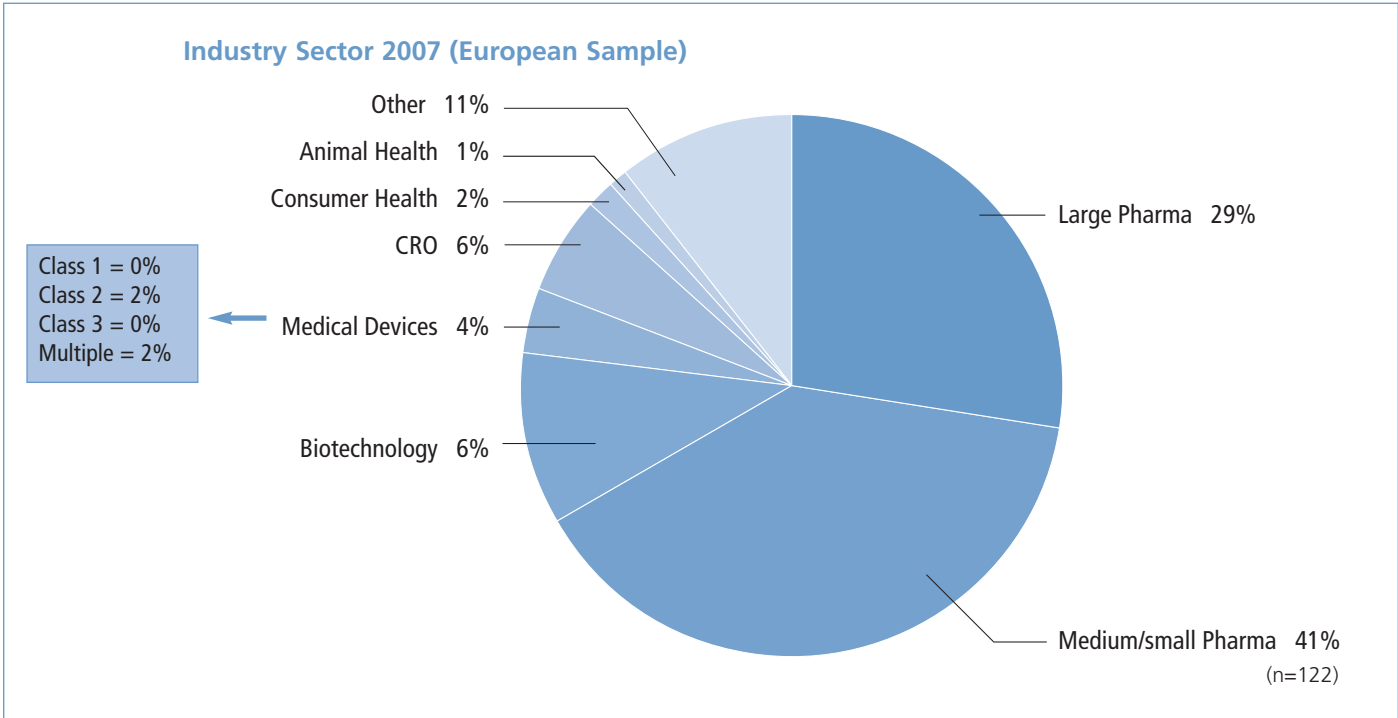
The countries included in the "Other" category (15%) are as follows: Austria, Belgium, China, Finland, Hungary, India, Ireland, Israel, Netherlands, Norway, Portugal, Spain, Sweden and Turkey. One percent of respondents came from each of these countries.

As in previous years, the total sample of respondents has been analyzed by region in order to show specific results from European countries as compared to the rest of the world. The results that follow show this analysis by region.

One-third (37%) work in large pharmaceutical companies with more than \$1 billion in revenue. Another third (33%) work in medium/small pharmaceutical companies with up to \$1 billion in revenue, and another 11% are in biotechnology companies. There are significantly more respondents from large pharmaceutical companies in 2007 (37%) than in 2006 (29%).

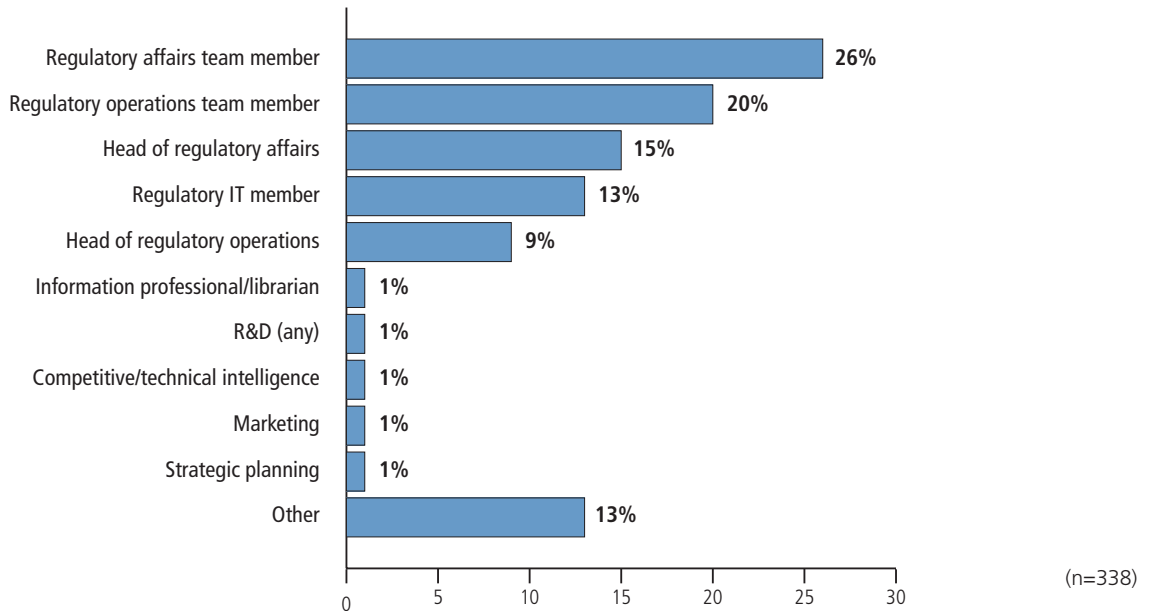


Among the respondents from European countries (n=122), slightly less than one third work in large pharmaceutical companies (29%) and four in ten work in medium/small pharmaceutical companies (41%). There are significantly fewer European respondents who work in large pharmaceutical companies (29%) than non-Europeans (41%), with significantly more working in medium/small companies.



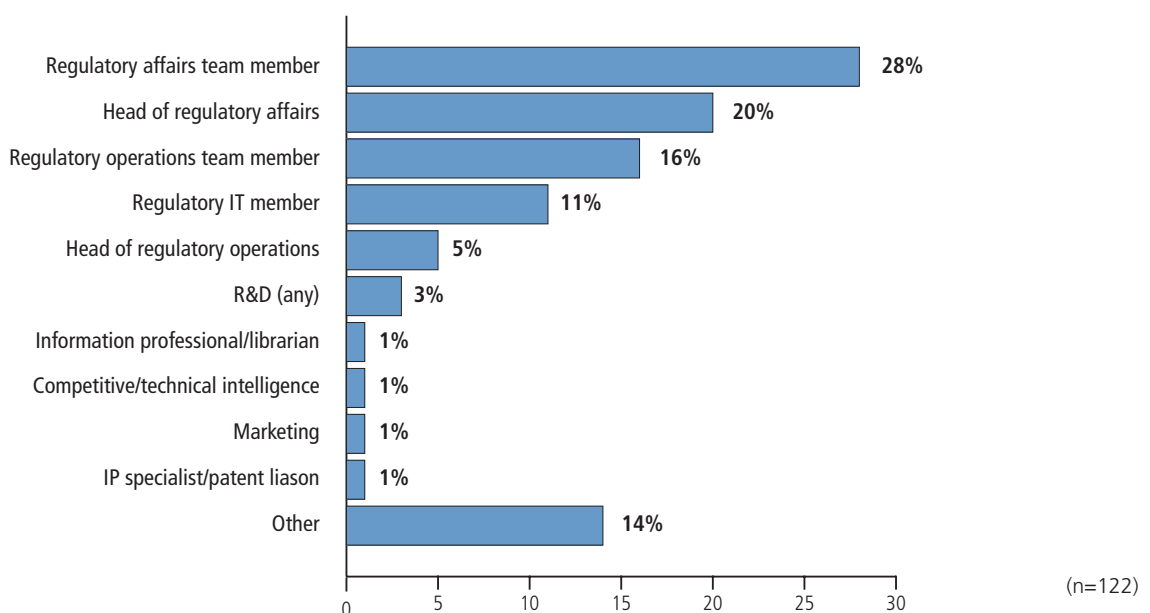
The majority (83%) of the survey respondents are in some type of regulatory affairs role. Of the respondents who work in other areas of the organization, most (77%) are involved in regulatory affairs submissions. Among respondents who chose "Other" were those in information technology/software, publishing, medical/technical writing, quality assurance, records management and project development.

Role within organization 2007 (Total Sample)



Eight in ten (80%) of the European respondents are in some type of regulatory affairs role. As in the total sample, most of the respondents who work in other areas of the organization are involved in regulatory affairs submissions (88%). Respondents who perform some "Other" role listed the following: information technology, quality assurance, and project development.

Role within organization 2007 (European Sample)



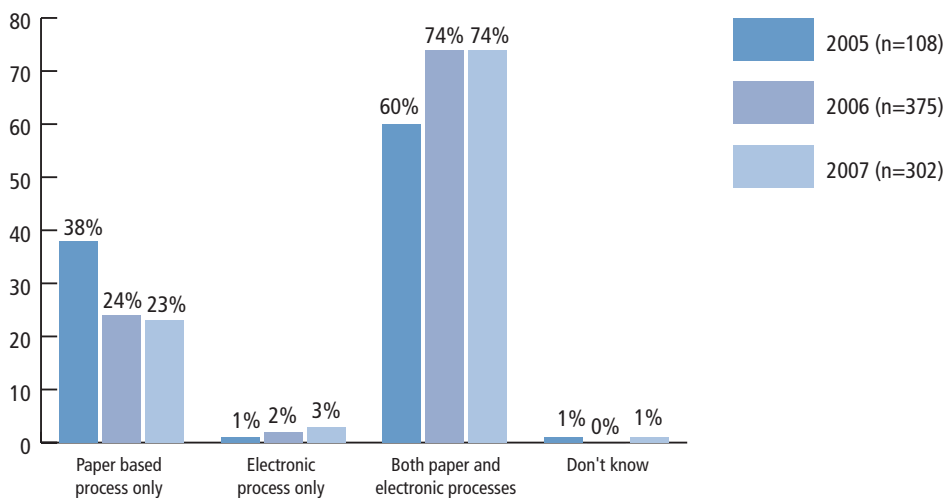
RESULTS

Technology Usage Trends

Almost all (90%) survey respondents make regulatory submissions (n=305). Three-fourths (75%) of respondents handle ALL regulatory submissions internally and the other one-fourth (24%) outsource some pieces of the process.

Three-fourths (74%) of respondents are currently using both paper and electronic processes.

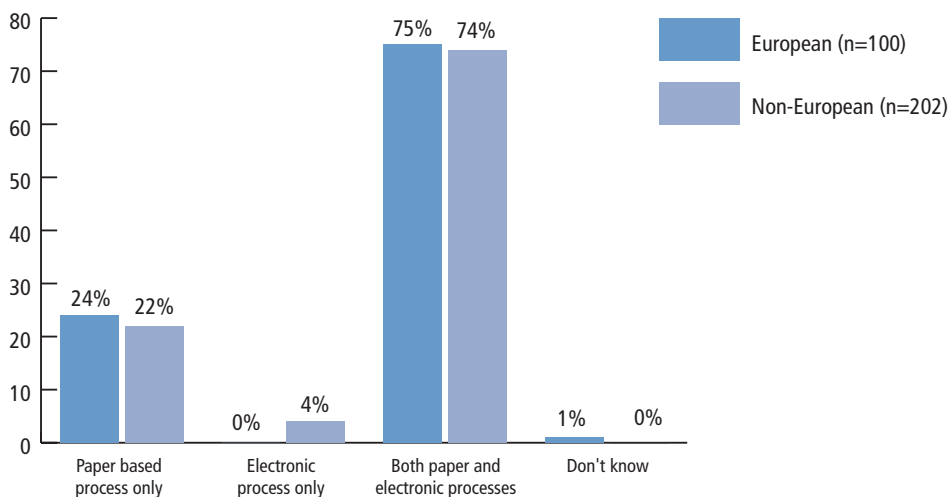
Current submission process 2007 (by Year)



Eight in ten of European respondents (82%) make regulatory submissions. This percentage is significantly lower when compared to all other countries, where 95% make regulatory submissions. As seen in the total sample, three-fourths (74%) of European respondents handle ALL regulatory submissions internally and the other one-fourth (26%) outsource some pieces of the process.

Three-fourths (75%) of respondents are currently using both paper and electronic processes.

Current submission process 2007 (by Region)



The following table shows the submission formats most likely to be used in two years' time for specific agencies. Respondents will most likely submit to the FDA via a Marketing Application (CTD), either in paper format (23%) or electronically (39%). Marketing Applications are most likely to be used in all other agencies listed.

Expectations for submissions in two years by Agency (n=302)

Agency	Paper Submission Format		Electronic Submission Format	
FDA	Marketing Application (CTD)	23%	Marketing Application (eCTD)	39%
	Marketing Application (Other)	2%	Marketing Application (Other)	2%
	IND (CTD)	20%	eIND (eCTD)	18%
	IND (Other)	7%	eIND (Other)	2%
	Other	12%	Other	8%
	Not applicable/don't know	37%	Not applicable/don't know	31%
Europe	Marketing Application (CTD)	36%	Marketing Application (full eCTD)	32%
	CTA (CTD)	7%	Marketing Application (partial eCTD)	14%
	CTA (IMPD)	10%	eCTA	6%
	Other	10%	Other	6%
	Not applicable/don't know	36%	Not applicable/don't know	42%
Japan	Marketing Application (CTD)	15%	Marketing Application (full eCTD)	12%
	Investigational Application (CTD)	3%	Marketing Application (partial eCTD)	4%
	Investigational Application (Other)	2%	Investigational Application	2%
	Other	4%	Other	2%
	Not applicable/don't know	76%	Not applicable/don't know	80%
Canada	Marketing Application (CTD)	21%	Marketing Application (eCTD)	24%
	INDS (CTD)	11%	Marketing Application (Other)	1%
	INDS (Other)	1%	eINDS (eCTD)	6%
	Other	8%	Other	4%
	Not applicable/don't know	59%	Not applicable/don't know	64%
Australia	Marketing Application (CTD)	16%	Marketing Application (eCTD)	11%
	Investigational Application (CTD)	3%	Marketing Application (Other)	1%
	Other	6%	Investigational Application (eCTD)	1%
	Not applicable/don't know	75%	Other	3%
			Not applicable/don't know	83%

The table below shows the submission formats most likely to be used in two years' time for specific agencies for European respondents only. Respondents will most likely submit to the FDA via a Marketing Application, either in paper format (28%) or electronically (29%). Marketing Applications are most likely to be used in all other agencies listed. When comparing Europe to all other countries, there were some significant differences. The highlighted and underlined percentages are significantly higher than those of non-European countries

Expectations for submissions in two years (European Sample) (n=100)

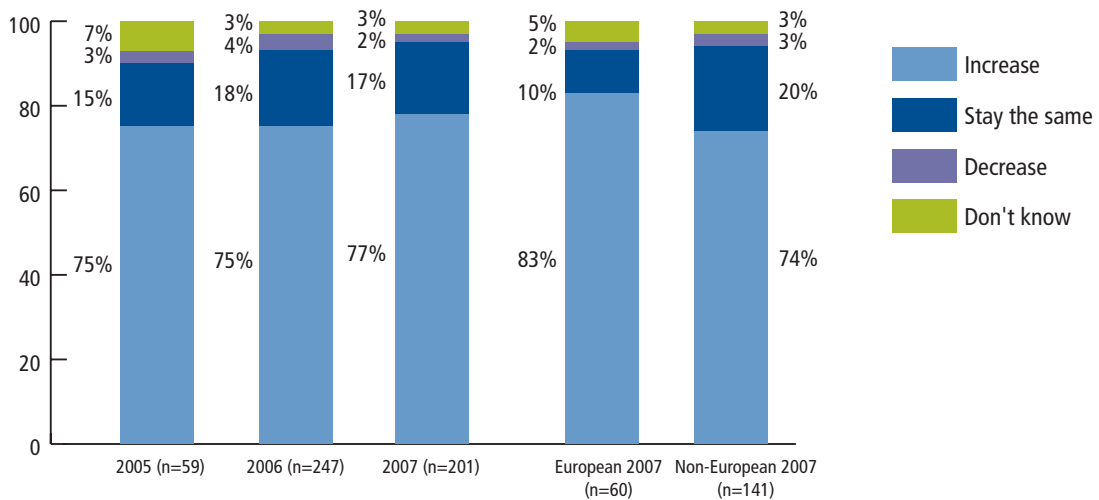
Agency	Paper Submission Format		Electronic Submission Format	
FDA	Marketing Application (CTD)	28%	Marketing Application (eCTD)	29%
	Marketing Application (Other)	2%	Marketing Application (Other)	3%
	IND (CTD)	11%	eIND (eCTD)	10%
	IND (Other)	1%	eIND (Other)	1%
	Other	8%	Other	6%
	Not applicable/don't know	50%	Not applicable/don't know	51%
Europe	Marketing Application (CTD)	<u>58%</u>	Marketing Application (full eCTD)	<u>42%</u>
	CTA (CTD)	4%	Marketing Application (partial eCTD)	<u>21%</u>
	CTA (IMPD)	8%	eCTA	2%
	Other	12%	Other	11%
	Not applicable/don't know	18%	Not applicable/don't know	24%
Japan	Marketing Application (CTD)	16%	Marketing Application (full eCTD)	12%
	Investigational Application (CTD)	1%	Marketing Application (partial eCTD)	2%
	Investigational Application (Other)	0%	Investigational Application	0%
	Other	3%	Other	1%
	Not applicable/don't know	80%	Not applicable/don't know	85%
Canada	Marketing Application (CTD)	21%	Marketing Application (eCTD)	19%
	INDS (CTD)	4%	Marketing Application (Other)	2%
	INDS (Other)	1%	eINDS (eCTD)	2%
	Other	6%	Other	3%
	Not applicable/don't know	68%	Not applicable/don't know	74%
Australia	Marketing Application (CTD)	<u>24%</u>	Marketing Application (eCTD)	<u>18%</u>
	Investigational Application (CTD)	3%	Marketing Application (Other)	2%
	Other	4%	Investigational Application (eCTD)	0%
	Not applicable/don't know	69%	Other	2%
			Not applicable/don't know	78%

Submissions Publishing Software

Two-thirds of respondents (67%) currently use submission publishing software; this percentage has remained the same since the previous year. About the same percentage of European respondents (60%) use submission publishing software.

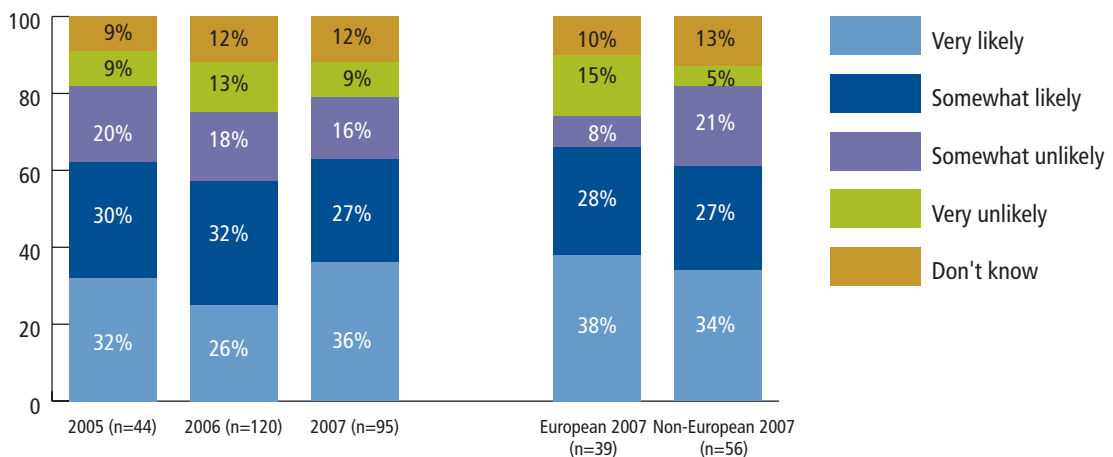
Three-fourths of respondents (77%) claim their use of this software is going to increase in the next two years. There are no significant differences between European and non-European respondents.

Future use of Publishing Software



Of those respondents not currently using submissions publishing software (n=95), one third (36%) are very likely to begin using it. About the same percentage of European respondents (38%) are very likely to begin using it. There are no significant differences between European and non-European respondents.

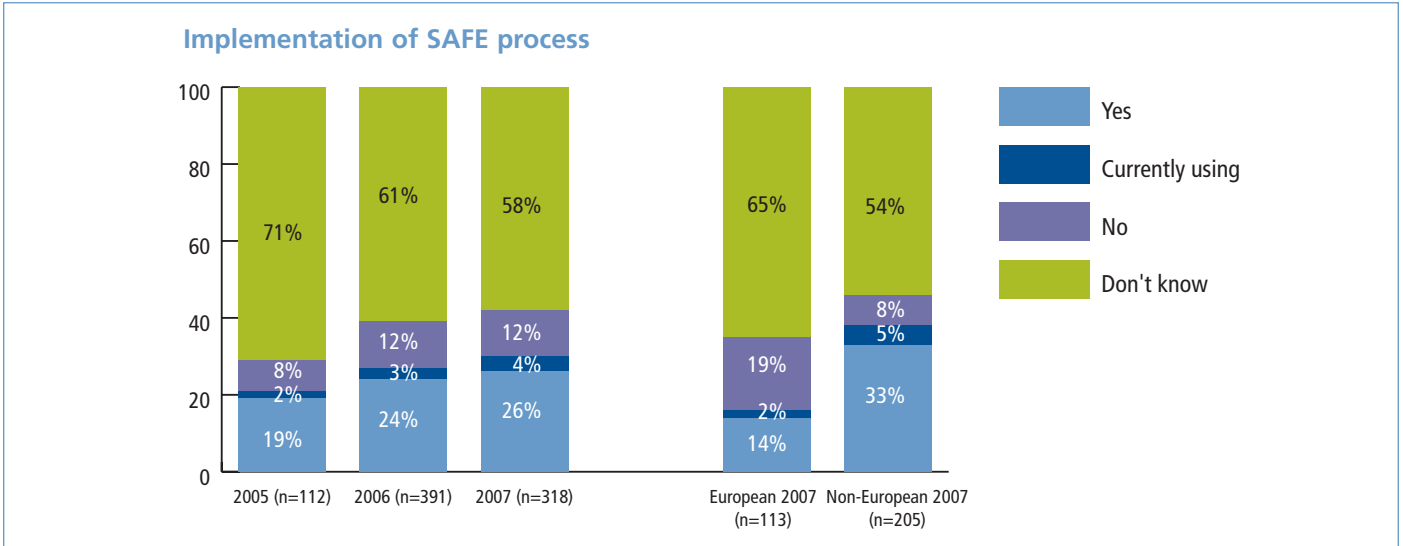
Likelihood of using Publishing Software



One-fourth of respondents (27%) stated they will use software within 1-2 years, significantly more than in 2006 (3%). An additional 32% will begin using software within the next year. One third (34%) of European respondents report the same timeframe.

Only 4% of respondents are currently using technology that supports the SAFE initiative. This percentage has not changed over the past year. An additional 26% plan to implement the technology in the future, and 58% don't know whether or not they will implement the process.

Significantly fewer European respondents plan to implement SAFE in the future, with 14% of Europeans planning this compared to 33% of those from other countries.

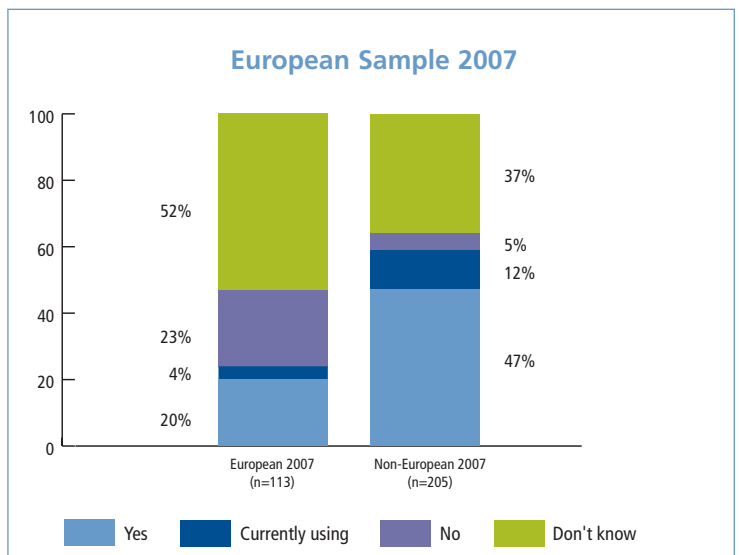
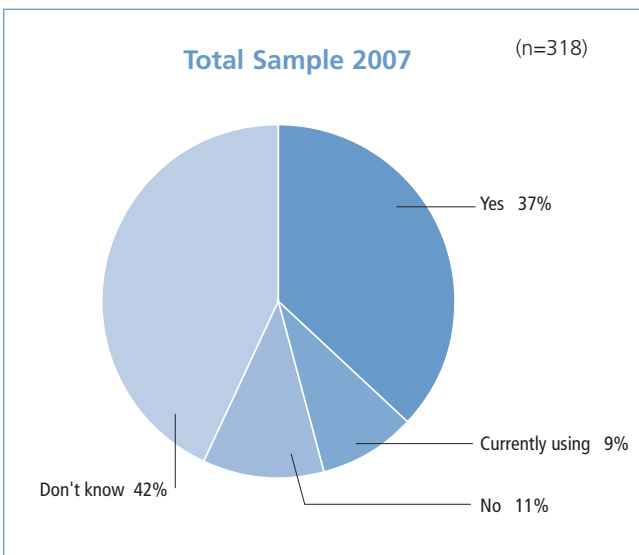


Of those who do not intend to implement technology that supports SAFE (n=37), the reasons include:

- Cost
- Other projects have priority
- Not needed in the organization
- Already have an internal system
- Aware, but still undecided whether or not to implement

More than one third of respondents (37%) plan to implement technology that supports the FDA Gateway. An additional 9% are currently using it. Four in ten (42%) don't know whether or not they will implement the technology. Significantly fewer European respondents (20%) than non-European respondents (47%) plan to implement technology that supports the FDA Gateway.

Implementation of FDA Gateway Technology



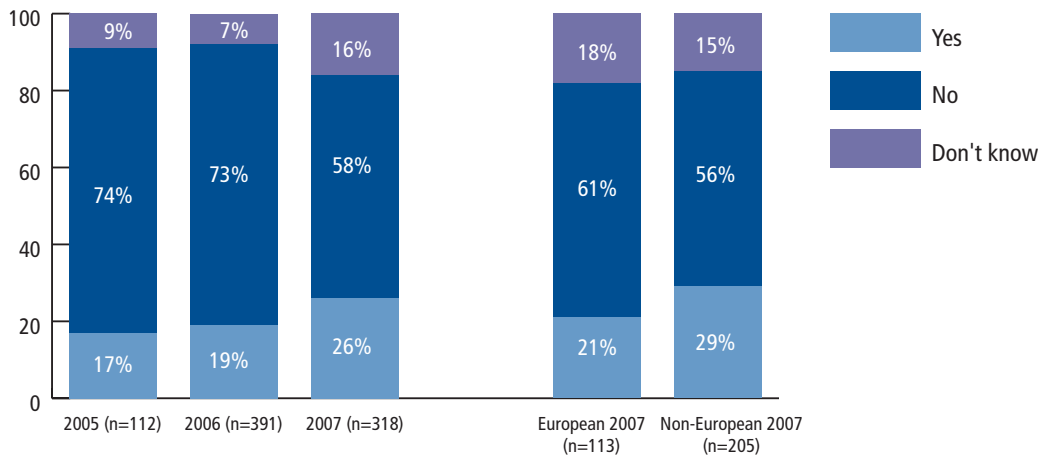
Of those who do not intend to implement technology that supports the FDA Gateway standard, and of those who do not know whether their organization will move in this direction, the reasons include:

- No plans for FDA submissions 16%*
- Not identified as a need/has not been discussed 10%
- Not relevant/applicable 10%
- Europe only, not in US 9%
- Topic is currently under discussion and may implement in the future 6%
- Will not consider this until it becomes a requirement 4%
- US company handles FDA submissions 4%
- Other projects have greater priority 3%
- Other 15%
- Don't know 30%

*Percents based on n=79 respondents who answered this question.

About six in ten respondents (58%) are not currently utilizing a digital signature process for their submissions, significantly fewer than the previous year (73%). Likewise, the percent that use this process (26%) is significantly higher than the previous year (19%). The distribution is similar across European and non-European respondents.

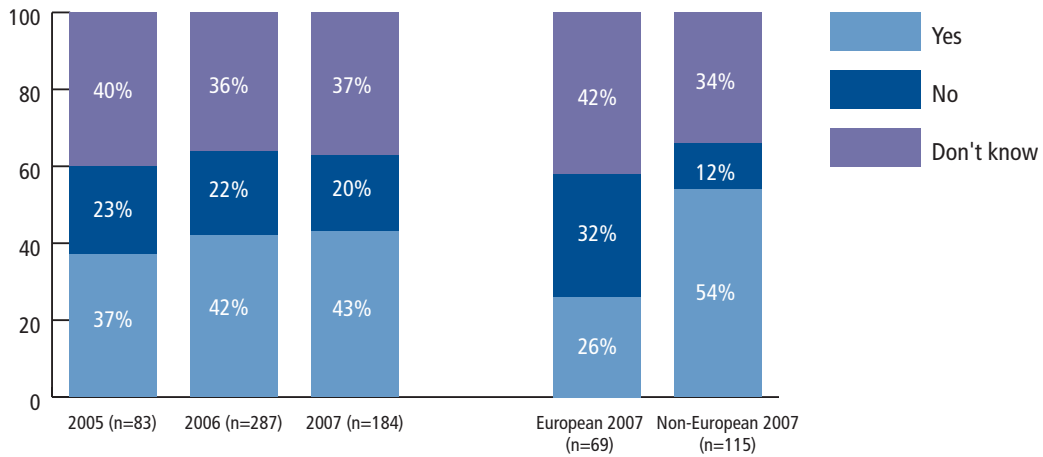
Currently using the Digital Signature Process



However, 43% of total respondents do plan to implement this process in the future. The same is not true for European respondents, where only 26% plan to implement a digital signature process in the future — significantly less than non-European respondents (54%).

Those who do not plan to implement the process stated it was not necessary in their current situation.

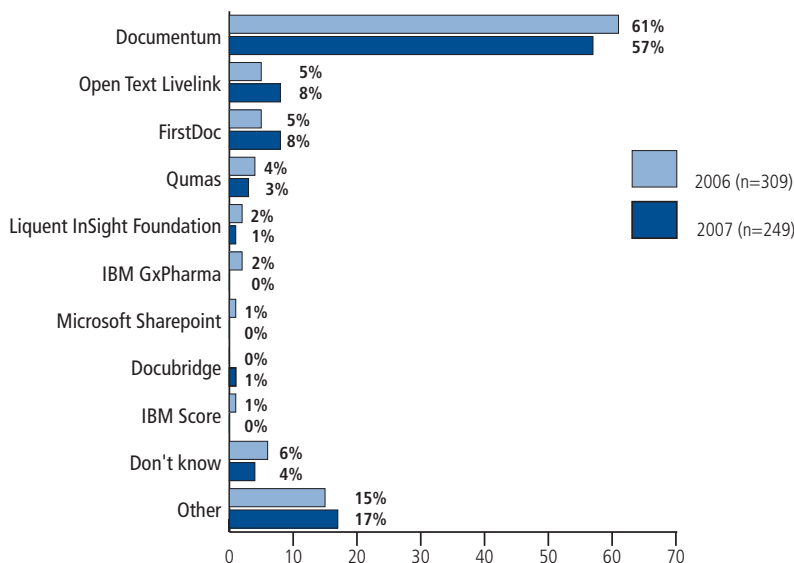
Future use of Digital Signature



Document Management

Three-fourths (74%) of respondents currently use a document management system (n=249). This percentage has remained the same over the past year. Of these, 57% use Documentum as their primary system (n=141).

Primary Document Management System (by Year)



Those included in the “other” category (n=43) listed the following as their primary document management system:

- Mastercontrol 14%
- Matrix One 12%
- Internal system 12%
- Lotus notes 5%
- SAP DMS 5%
- Document management and publishing system 5%
- Other 49%

One third (35%) plan to upgrade their current version (n=87); this percentage is similar to the previous year, in which 38% planned to upgrade their current version.

- 14% plan to upgrade within 3 months, another 29% plan to upgrade within 4-6 months, and 29% plan to upgrade within 7-12 months.

The table below shows the version number of the primary document management system that is currently used at the organization, as well as the version to which the organization will upgrade in the next year.

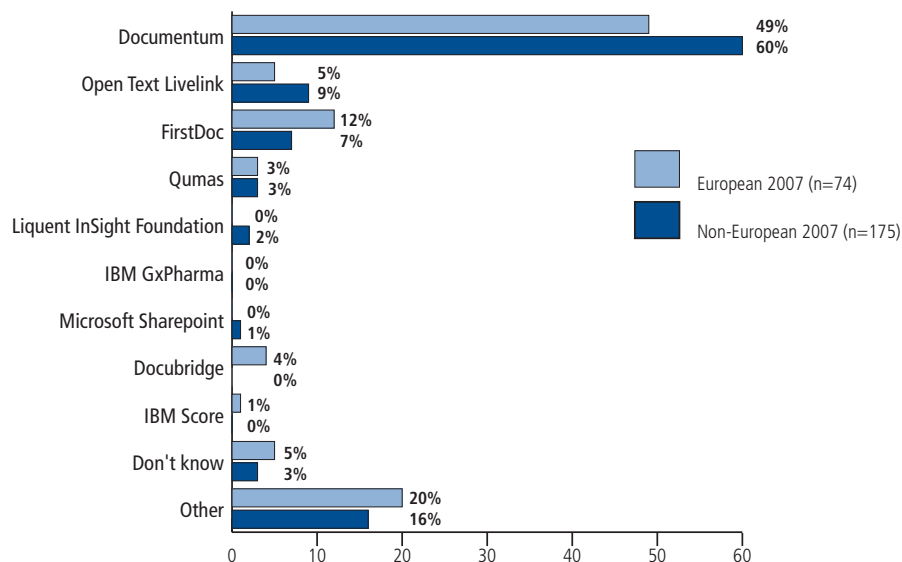
Current Versions of Primary Document Management Systems and Expected Upgrades (Total Sample)

Primary Document Management System	Version Currently Using	%	Version to which will upgrade	%
Documentum (n=141)	v.1	1%	v.3	4%
	v.2	1%	v.4	2%
	v.3	4%	v.5	17%
	v.4	13%	v.6	6%
	v.5	35%	Other	10%
	Other	4%	Don't know	60%
	Don't know	42%		
Open Text Livelink (n=20)	v.1	5%	v.9	40%
	v.9	70%	Don't know	60%
	Don't know	25%		
FirstDoc (n=21)	v.1	5%	v.4	33%
	v.2	5%	v.5	8%
	v.3	10%	Don't know	58%
	v.4	38%		
	Other	5%		
Qumas (n=7)	Don't know	38%		
	v.4	14%	Don't know	100%
Docubridge (n=3)	Don't know	86%		
	v.3	33%	v.2	50%
Liquent InSight Foundation (n=3)	Don't know	67%	Don't know	50%
	Don't know	100%	v.1	50%
			Don't know	50%

Six in ten (61%) of European respondents currently use a document management system, significantly less than the 81% of non-European respondents who use one.

About half of European respondents (49%) use Documentum as their primary electronic document management system. There were no significant differences in the electronic document management systems used by European respondents as compared to non-Europeans.

Primary Document Management System (By Region)



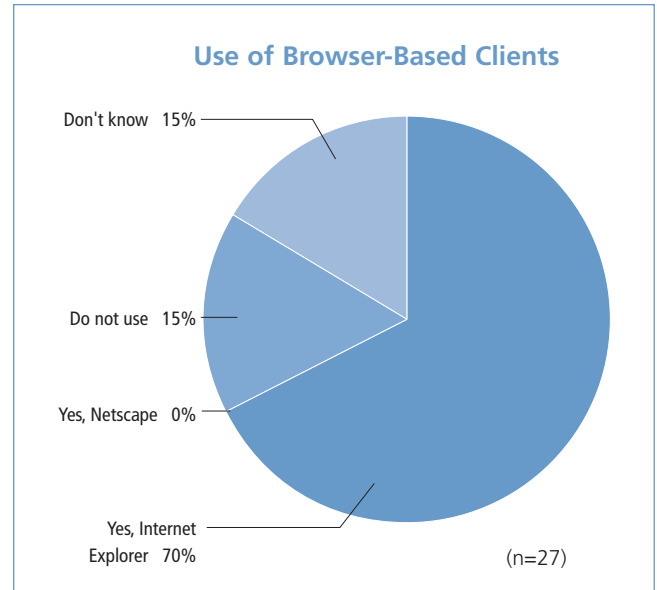
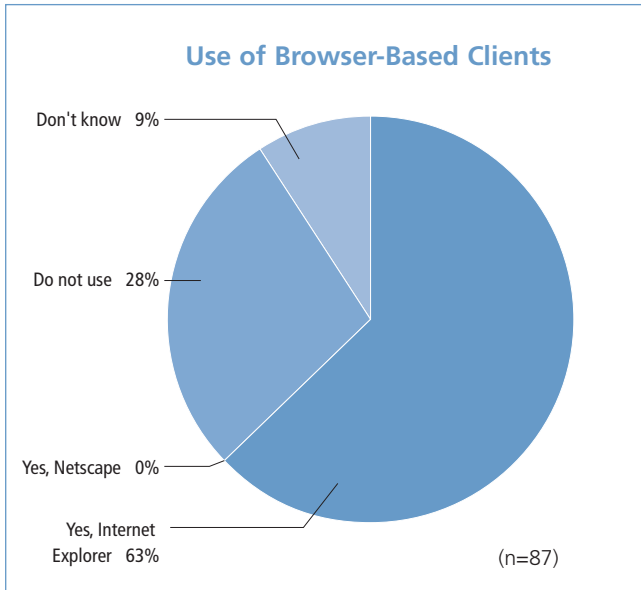
One-third (36%) of European respondents plan to upgrade their current version (n=27). Of these, 11% plan to upgrade within 3 months, another 33% plan to upgrade within 4-6 months, and an additional 30% plan to upgrade within 7-12 months.

The table below shows the version number of the primary document management system that is currently used at the organization for European respondents only, as well as the version to which the organization will upgrade in the next year.

Current Versions of Primary Document Management Systems and Expected Upgrades (European Sample)

Primary Document Management System	Version Currently Using	%	Version to which will upgrade	%
Documentum (n=36)	v.2	6%	v.5	20%
	v.4	11%	Other	10%
	v.5	25%	Don't know	70%
	Other	6%		
	Don't know	53%		
Open Text Livelink (n=4)	v.9	50%	Don't know	100%
	Don't know	50%		
FirstDoc (n=9)	v.1	11%	v.4	50%
	v.4	44%	Don't know	50%
	Don't know	44%		
Qumas (n=2)	Don't know	100%	Don't know	100%
Docubridge (n=3)	v.3	33%	v.2	50%
	Don't know	67%	Don't know	50%

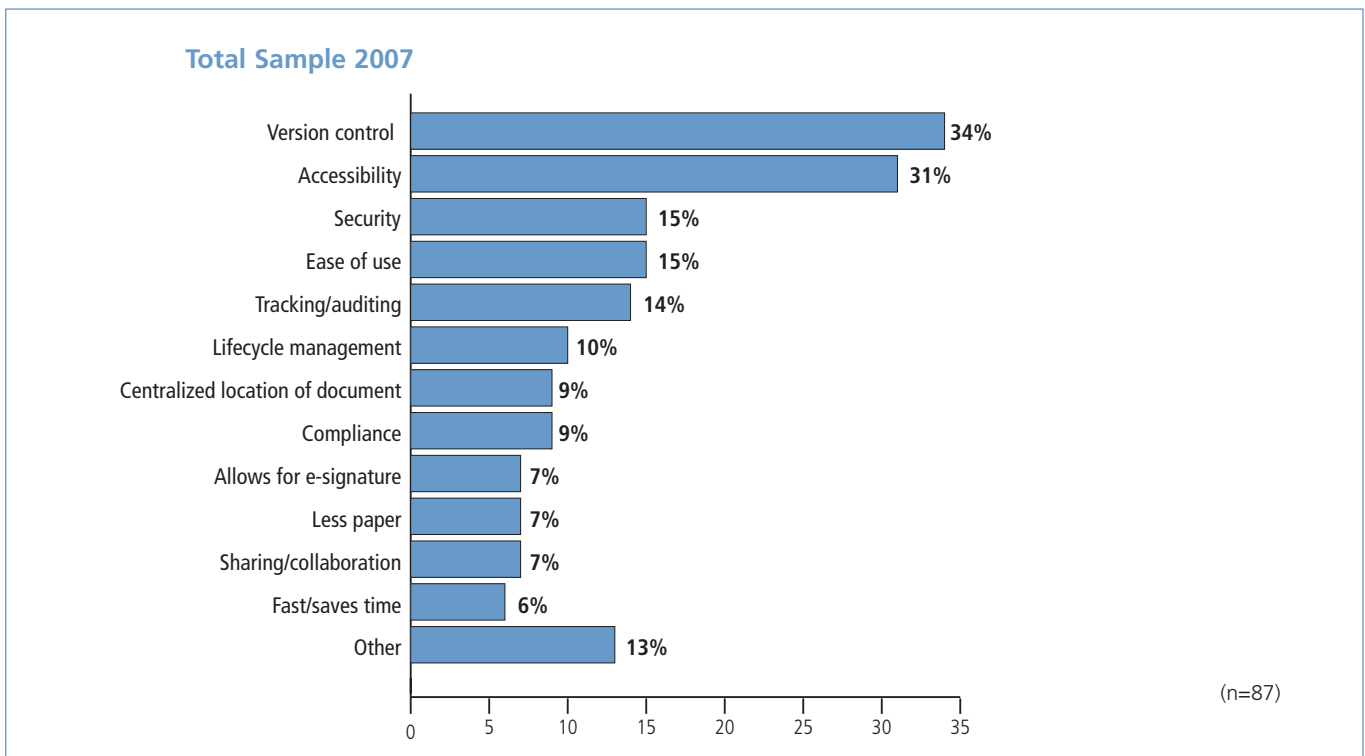
Of those who use electronic document management systems (and who plan to upgrade their current version of this system), two-thirds (63%) use a browser-based client. In the total sample, all use Microsoft® Internet Explorer. In Europe, we see the same distribution, with no significant differences between European and non-European respondents.



One-third (34%) of respondents stated that version control was the primary benefit of a document management system, and three in ten (31%) stated that accessibility of documents (i.e., access from multiple sites and global access to documents) was the primary benefit. These percentages are similar to those reported last year.

Primary Benefits of a Document Management System

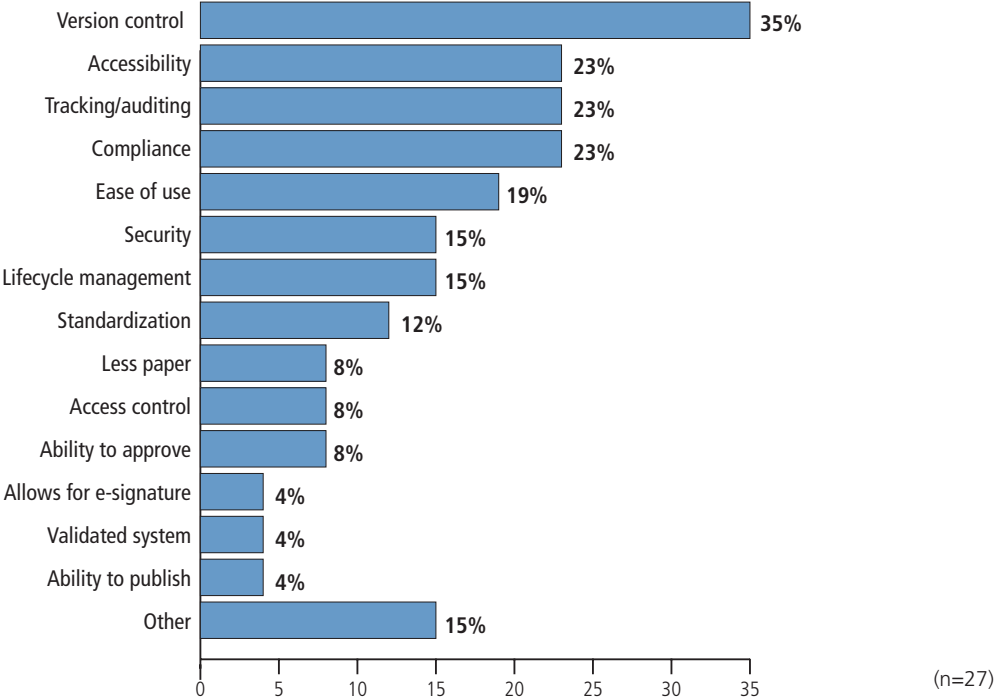
Open-ended question (Multiple Responses)



For European respondents (n=27), the primary benefit of a document management system is similar to the total sample: one-third (35%) of respondents stated that version control was the primary benefit of a document management system. Two in ten (23%) stated that accessibility of documents was the primary benefit, and the same percentage felt it was tracking/auditing capabilities and compliance.

Primary Benefits of a Document Management System
Open-ended question (Multiple responses)

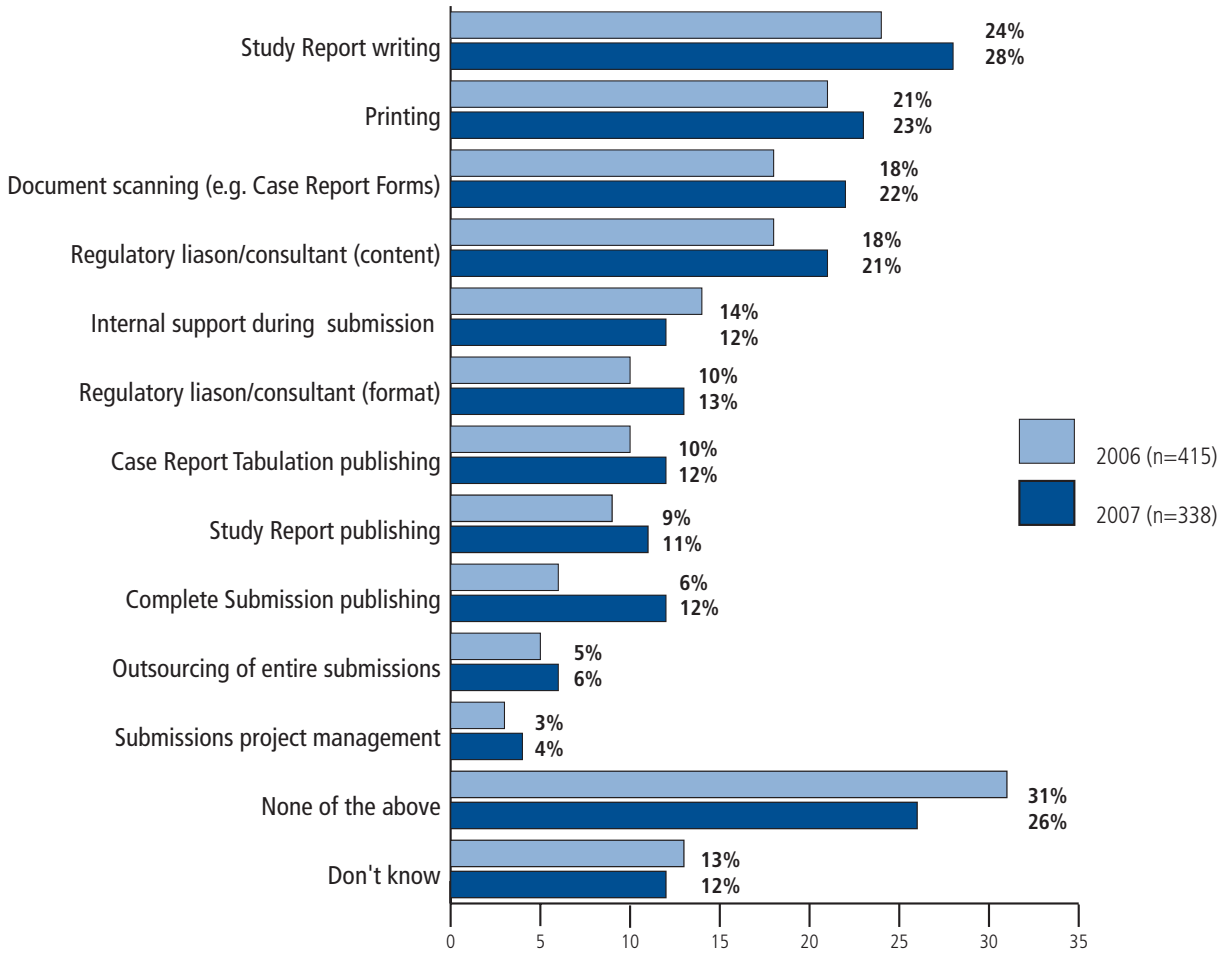
European Sample 2007



Regulatory Operations Outsourcing Trends

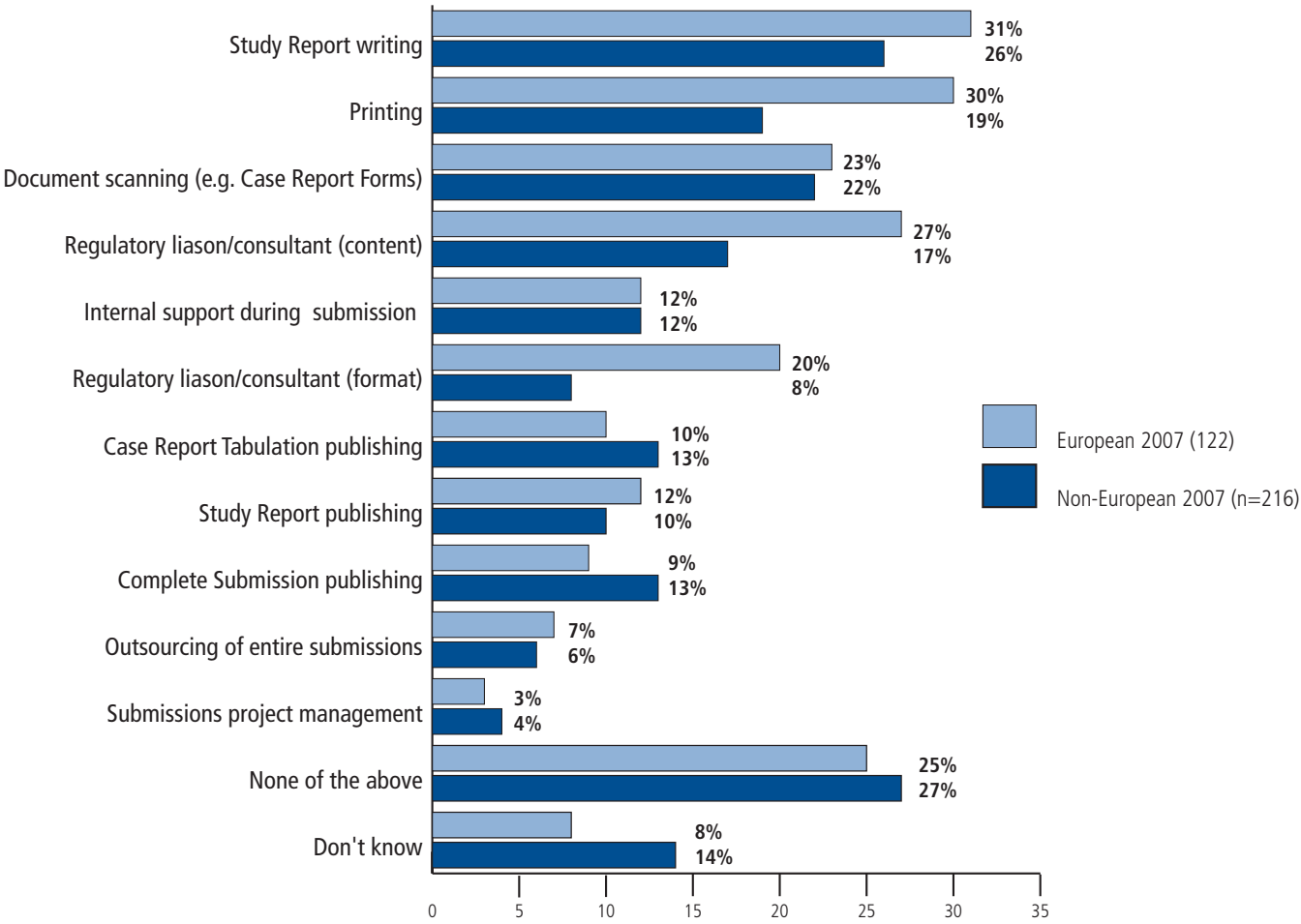
Currently, 26% of respondents do not outsource anything, 28% have outsourced study report writing, and another one-fifth have outsourced printing (23%), document scanning (22%), and have used a regulatory consultant for content (21%). In 2007, significantly more outsourced complete submission publishing (12%) compared to last year (6%).

Operations Currently Outsourced



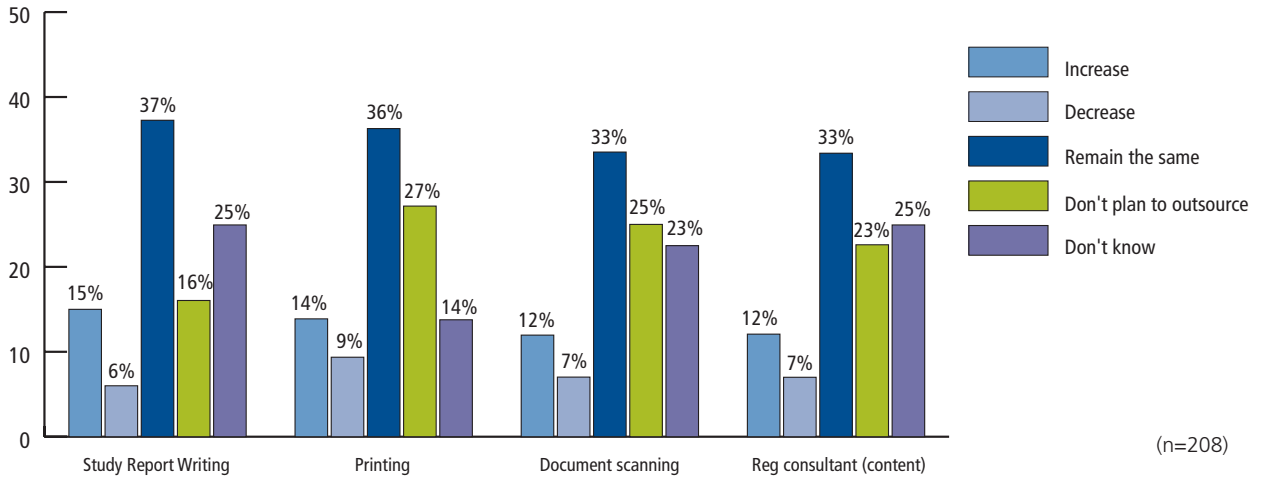
Currently, 25% of European respondents do not outsource anything. Three in ten have outsourced study report writing and printing. Significantly more European respondents outsource printing and regulatory liaisons, for both format and content.

Operations Currently Outsourced



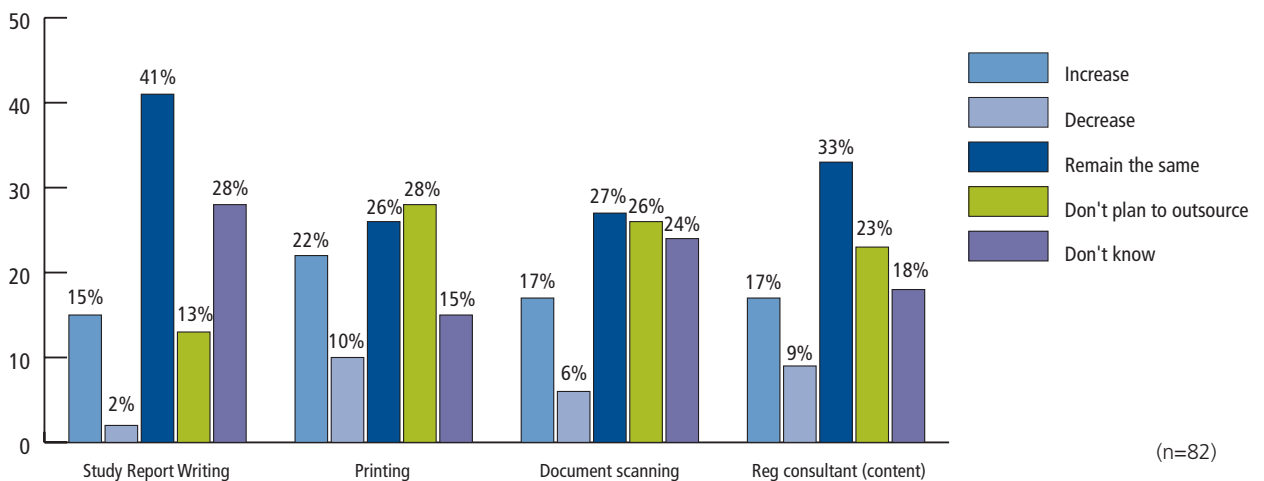
For the four main operations currently being outsourced — study report writing, printing, document scanning and regulatory consultant (content) — one third of respondents plan to keep the level of outsourcing the same. The percentage of respondents who plan to increase the level of printing outsourcing has significantly increased, from 8% in 2006 to 14%.

Change in Level of Outsourcing 2007 (Total Sample)



Four in ten (41%) European respondents plan to keep the level of outsourcing the same for study report writing. One third (33%) will not change the level of outsourcing to regulatory consultants (content). Significantly more European respondents (22%) plan to increase the level of printing outsourcing when compared to non-Europeans (10%).

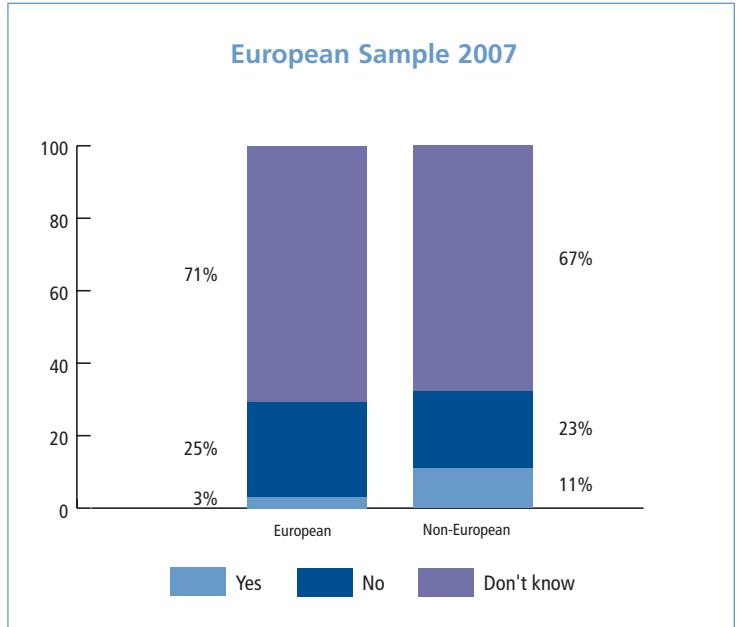
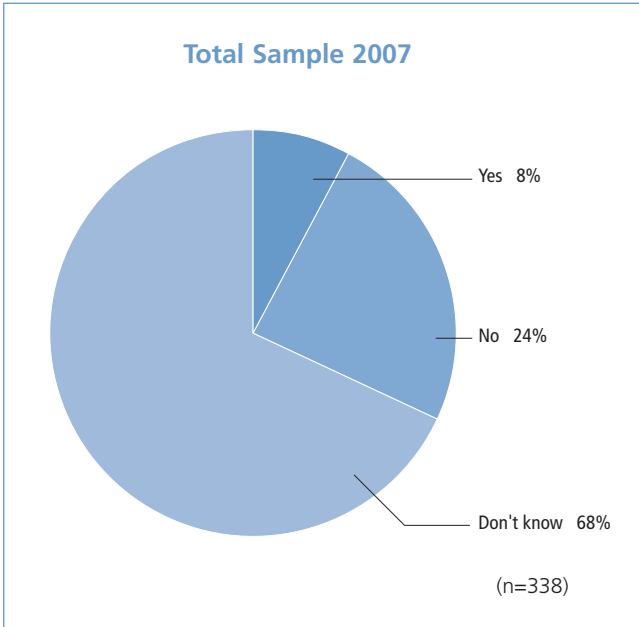
Change in Level of Outsourcing 2007 (European Sample)



Regulatory Trends

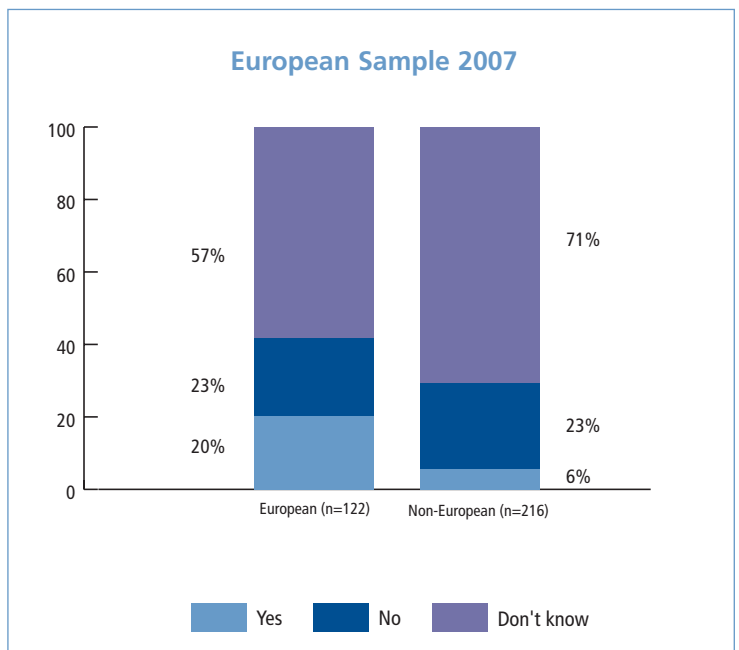
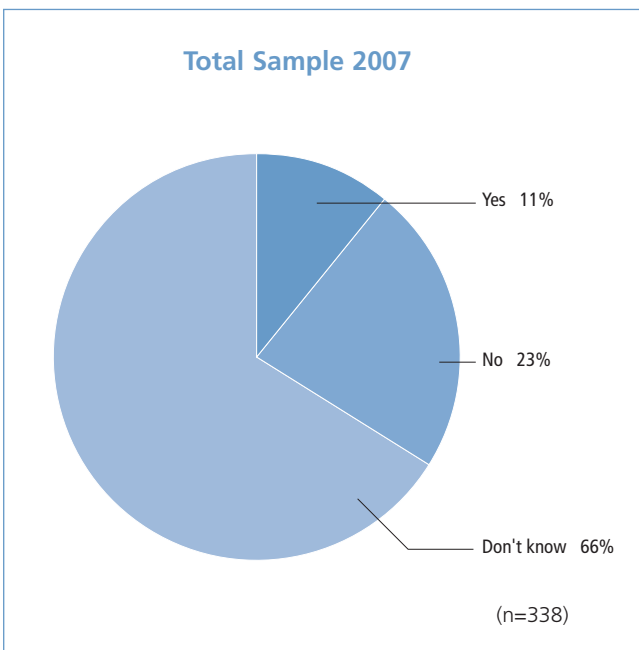
Eight percent of respondents plan to implement new or replacement solutions for the HL7's Regulated Product Submission (RPS) format within the next two years. This is significantly less than 2006, where 18% reported this intention. Three percent of European respondents plan to adopt HL7 RSP, significantly fewer than non-European respondents (11%).

HL7's Regulated Product Submission (RPS)



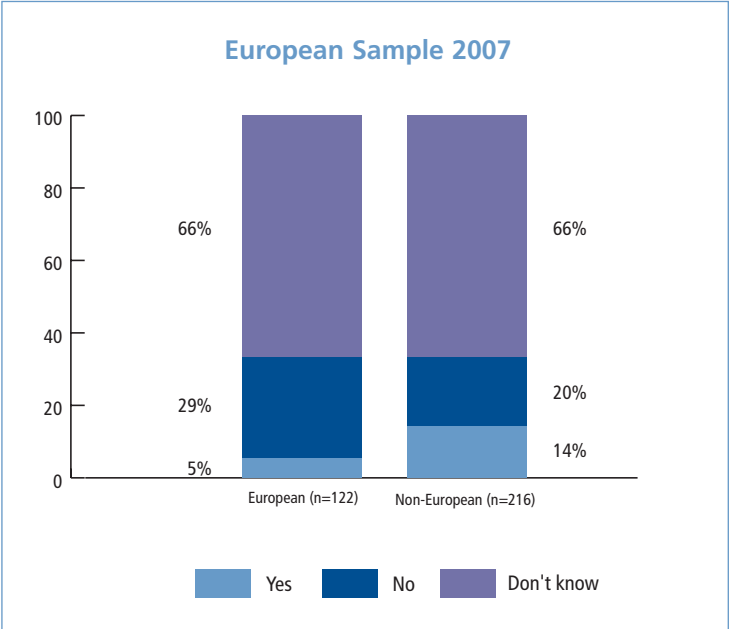
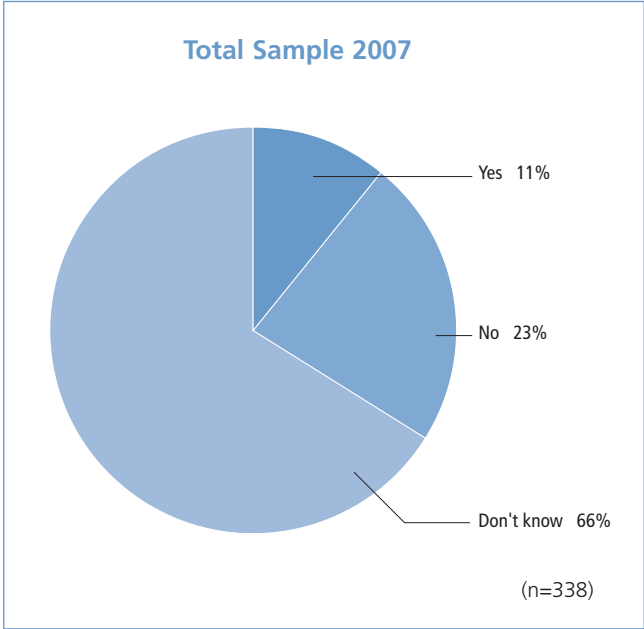
One in ten (11%) respondents report that their organization plans to adopt the EVMPD standard. This percentage is significantly lower than in 2006, where 22% reported this intention. Two in ten (20%) European respondents report that their organization plans to adopt the EVMPD standard, significantly more than non-European respondents (6%).

EVMPD (EudraVigilance Medical Product Dictionary)



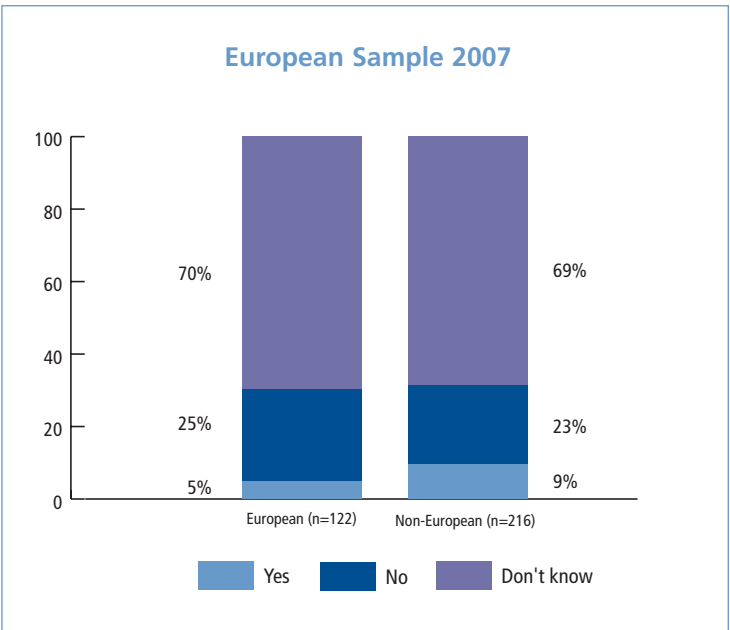
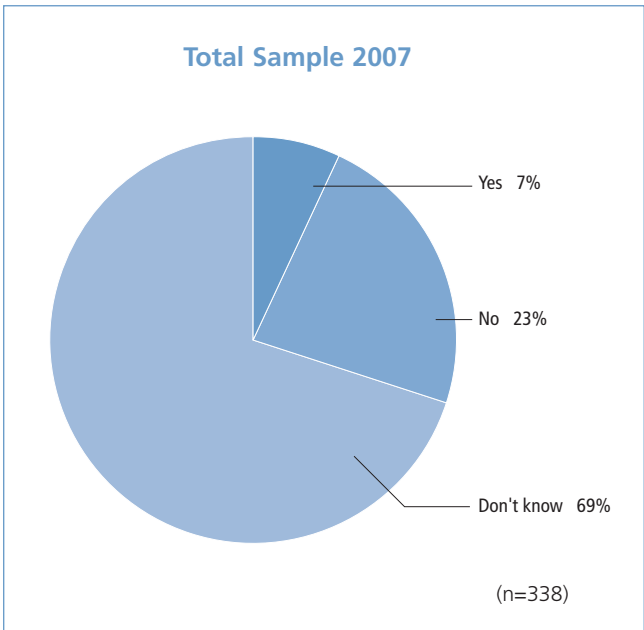
One in ten (11%) respondents plan to adopt the Study Data Tabulation Model (SDTM) standard. This percentage is significantly lower than in 2006, where 18% reported this intention. Five percent of European respondents plan to adopt the SDTM standard, significantly fewer than non-European respondents (14%).

SDTM (Study Data Tabulation Model)



Seven percent of respondents report that their organization plans to adopt the Structured Protocol Document (SPD) standard, significantly less than 2006, where 15% reported this intention. Five percent of European respondents report that their organization plans to adopt the SPD standard. There are no significant differences from non-Europeans.

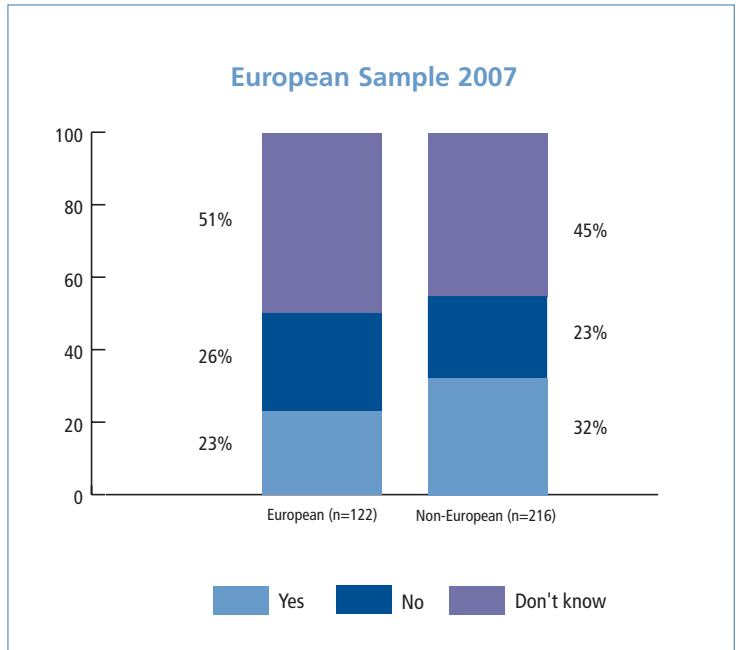
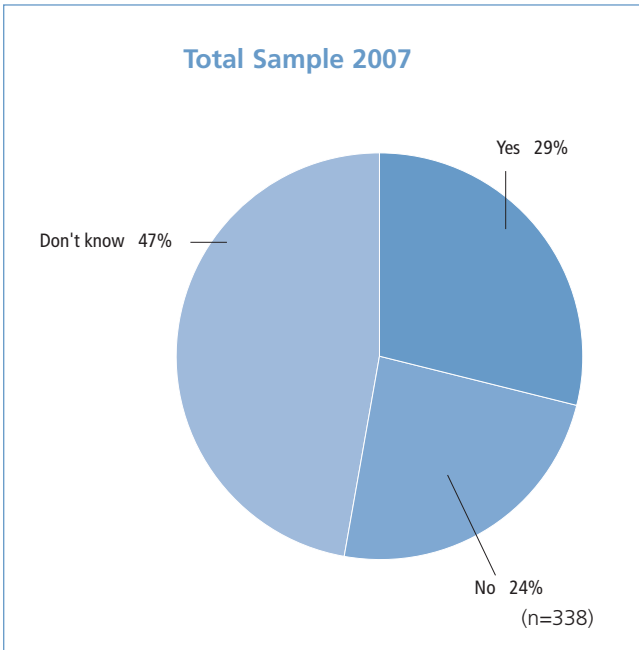
SPD (Structured Protocol Document)



Three in ten (29%) respondents report that their organization plans to adopt SPL labeling management within the next two years.

About one quarter (23%) of European respondents report that their organization plans to adopt SPL labeling management. There are no significant differences from non-Europeans.

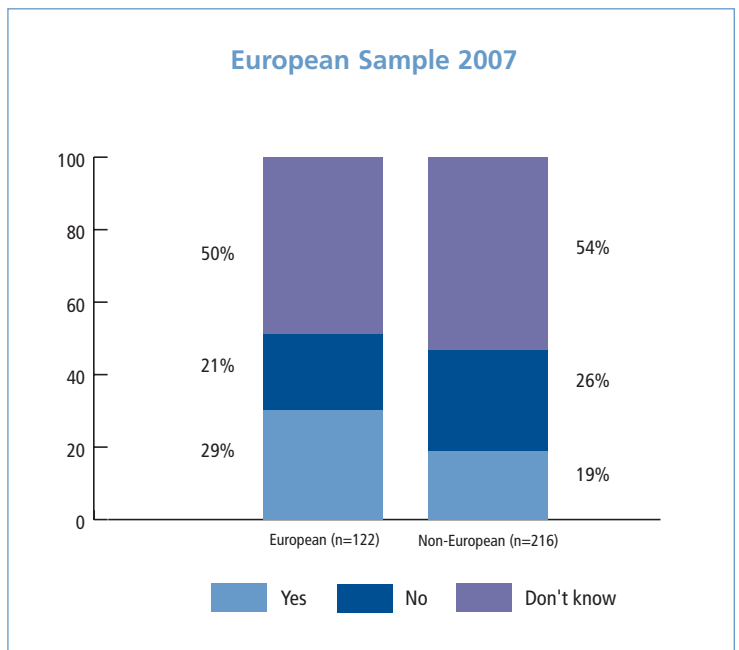
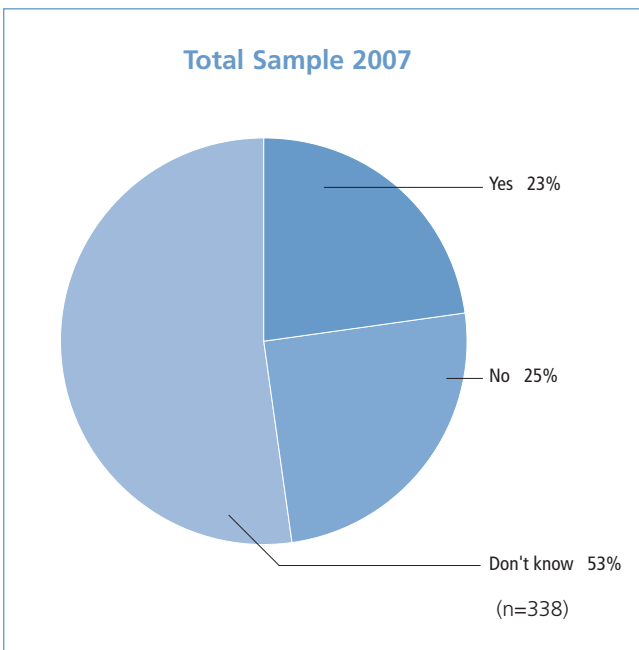
Labeling Management (SPL)



About one quarter (23%) of respondents report that their organization plans to adopt PIM labeling management within the next two years.

Three in ten (29%) European respondents report that their organization plans to adopt PIM labeling management. There are no significant differences from non-Europeans.

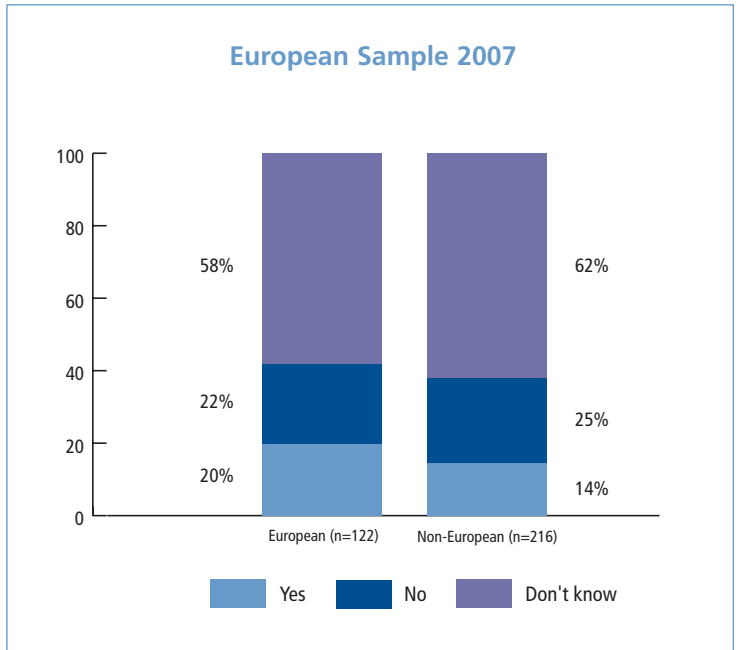
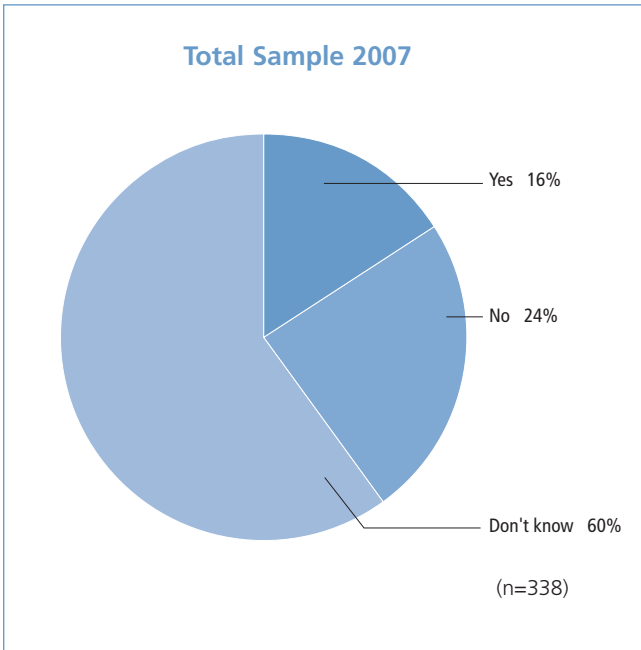
Labeling Management (PIM)



Sixteen percent of respondents report that their organization plans to adopt Commitment/Correspondence Management. One quarter (24%) do not plan to adopt this solution; this percentage is significantly higher than in 2006 (12%).

Two in ten (20%) of European respondents plan to adopt this feature. There are no significant differences between European and non-European respondents

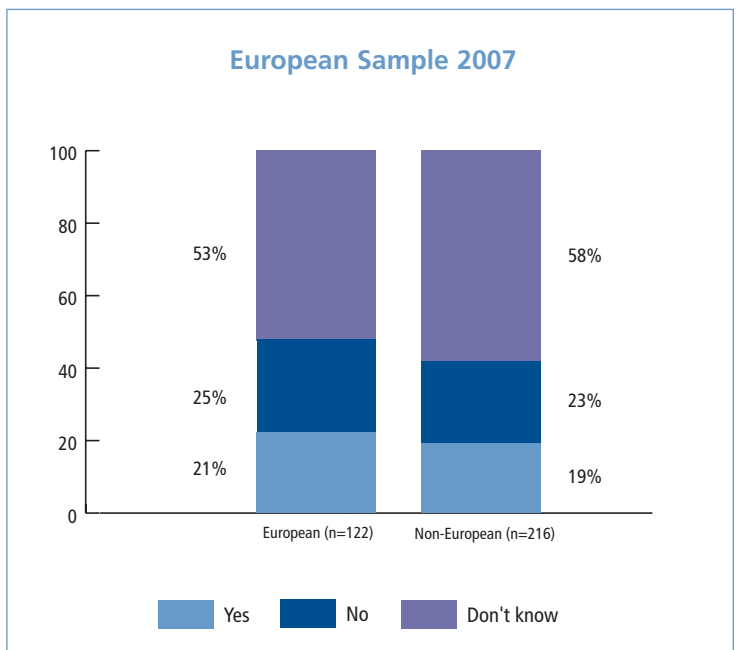
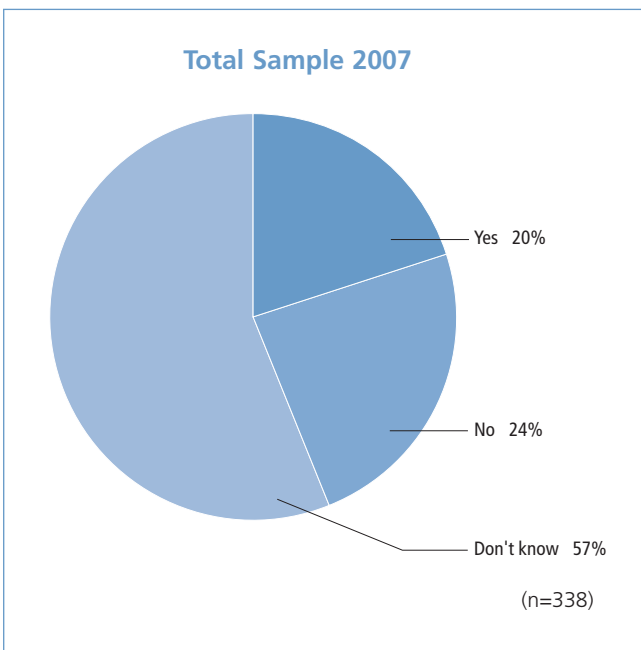
Commitment/Correspondence Management



Two in ten (20%) respondents plan to adopt Submission Quality Management. One quarter (24%) do not plan to adopt this solution; this is significantly lower than in 2006 (12%).

Two in ten (21%) of European respondents plan to adopt Submission Quality Management. There are no significant differences between European and non-European respondents.

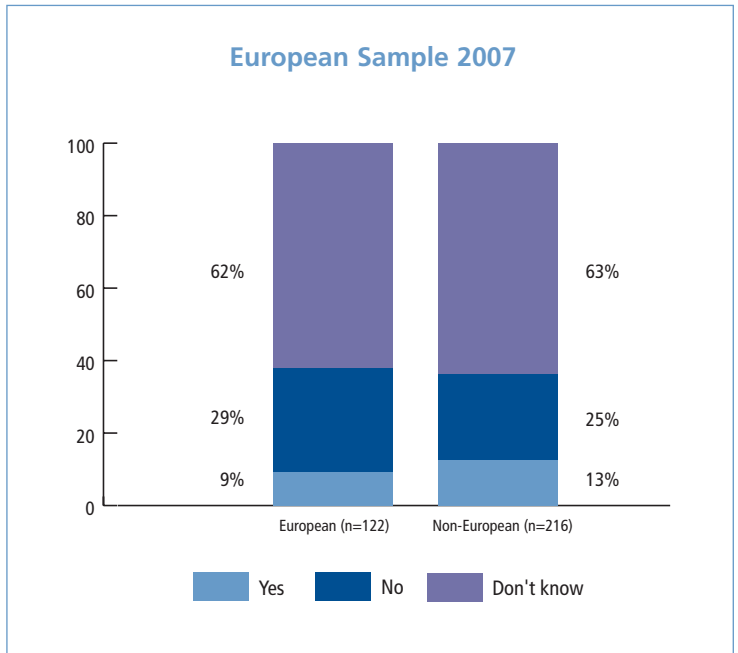
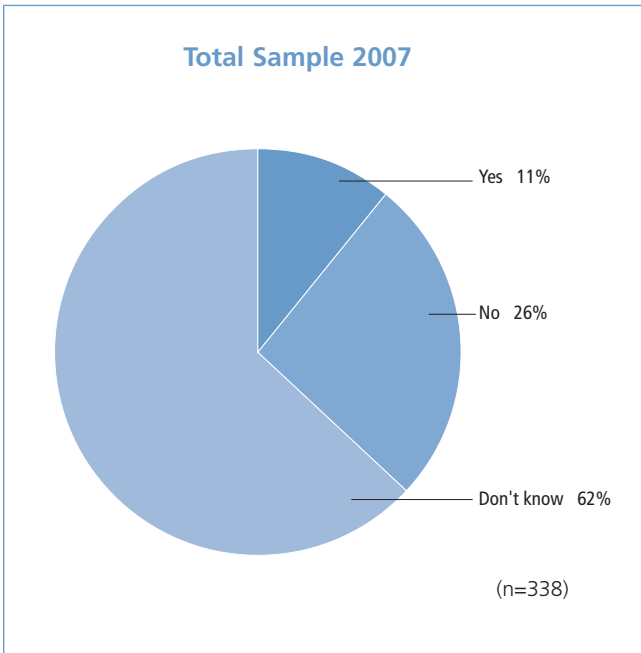
Submission Quality Management



One in ten (11%) respondents plan to adopt a Regulatory Product Team or Executive Dashboard within the next two years. This percentage is significantly lower than in 2006, where 54% reported this intention. Likewise, the percent who do not plan to adopt a Regulatory Product Team is significantly higher in 2007.

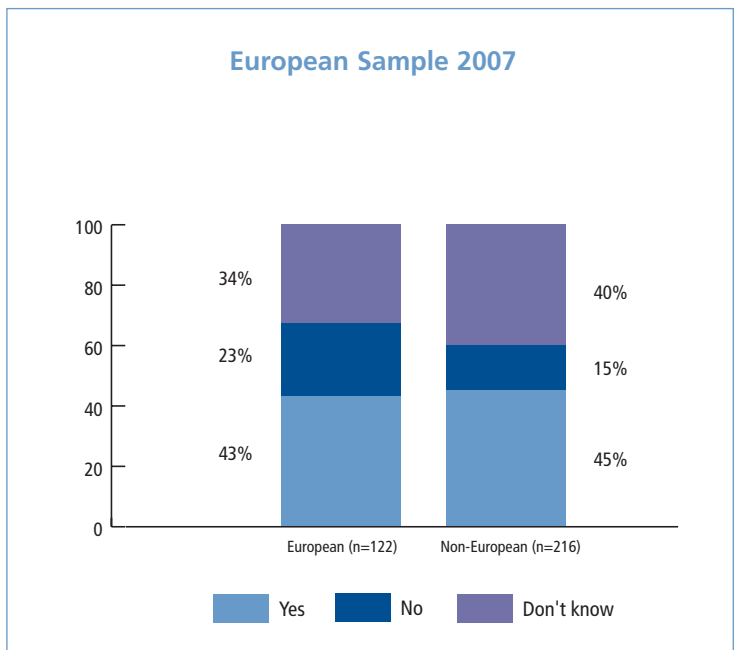
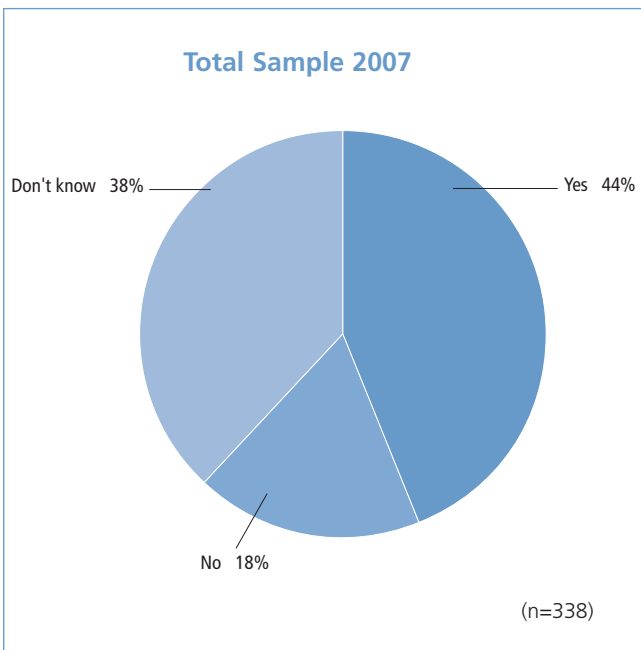
About one in ten (9%) European respondents plan to adopt a Regulatory Product Team or Executive Dashboard within the next two years. There are no differences between European and non-European respondents.

A Regulatory Product Team/Executive Dashboard



Four in ten (44%) respondents report that their organization plans to adopt an eCTD Viewer within the next two years. This is significantly higher than in 2006, where 32% reported this intention. Four in ten (43%) European respondents will adopt an eCTD Viewer. There are no differences between European and non-European respondents.

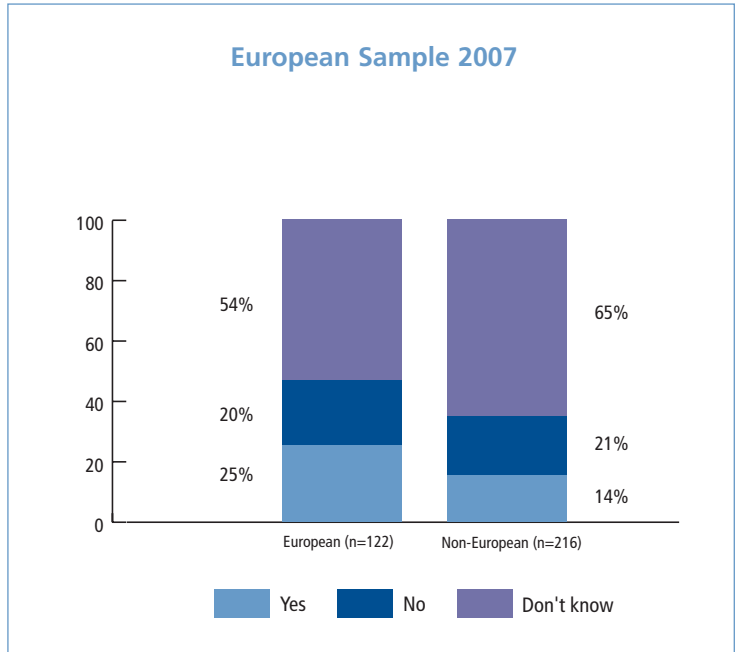
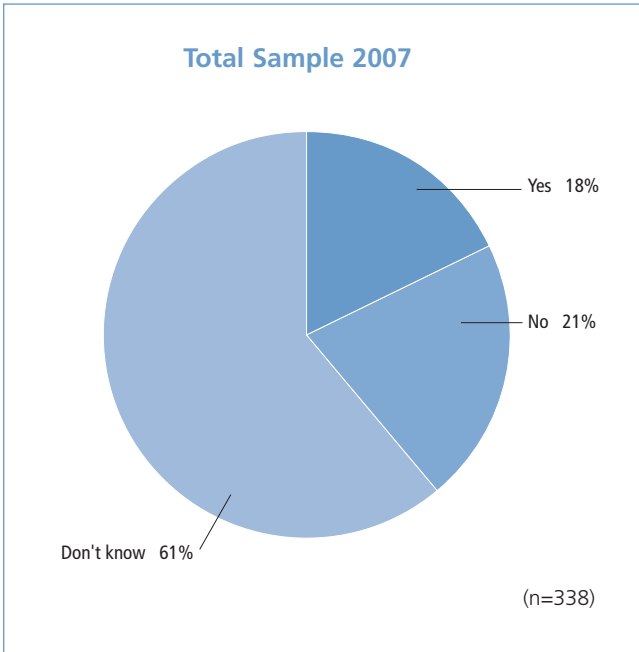
An eCTD Viewer



Two in ten (18%) respondents plan to adopt Pharmacovigilance within the next two years.

One quarter (25%) of European respondents plan to adopt Pharmacovigilance within the next two years. This percentage is significantly higher than for non-European respondents (14%).

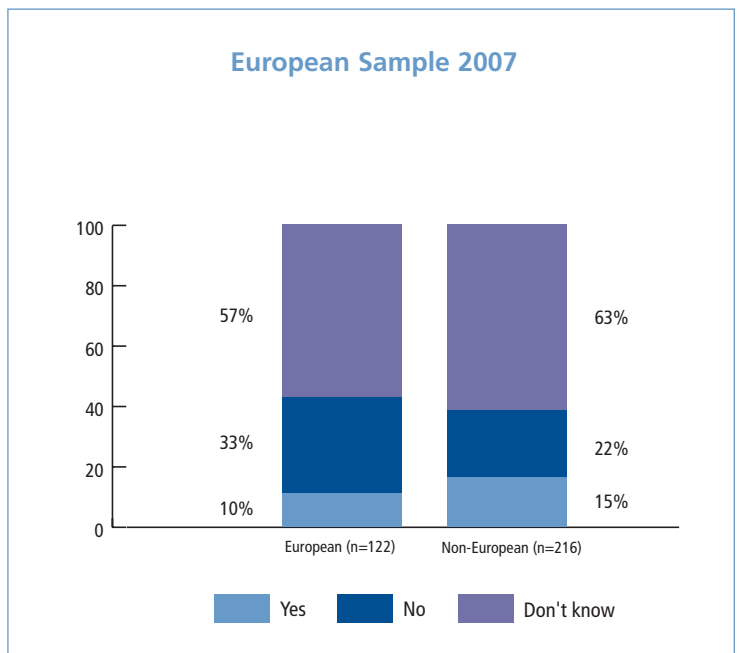
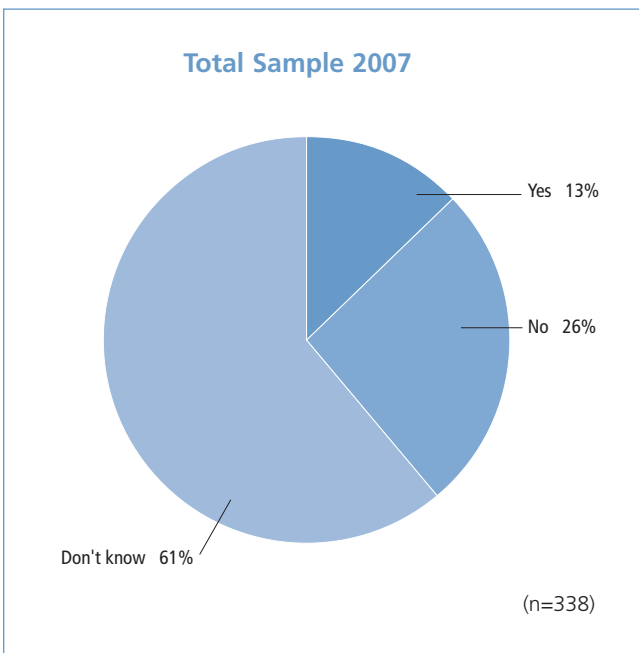
Pharmacovigilance



One in ten (13%) respondents plan to adopt Clinical Trial Safety Monitoring within the next two years.

About the same percentage of European respondents (10%) plan to adopt Clinical Trial Safety Monitoring within the next two years. Significantly more European respondents (33%) do not plan to adopt Clinical Trial Safety Monitoring when compared to non-Europeans (22%).

Clinical Trial Safety Monitoring



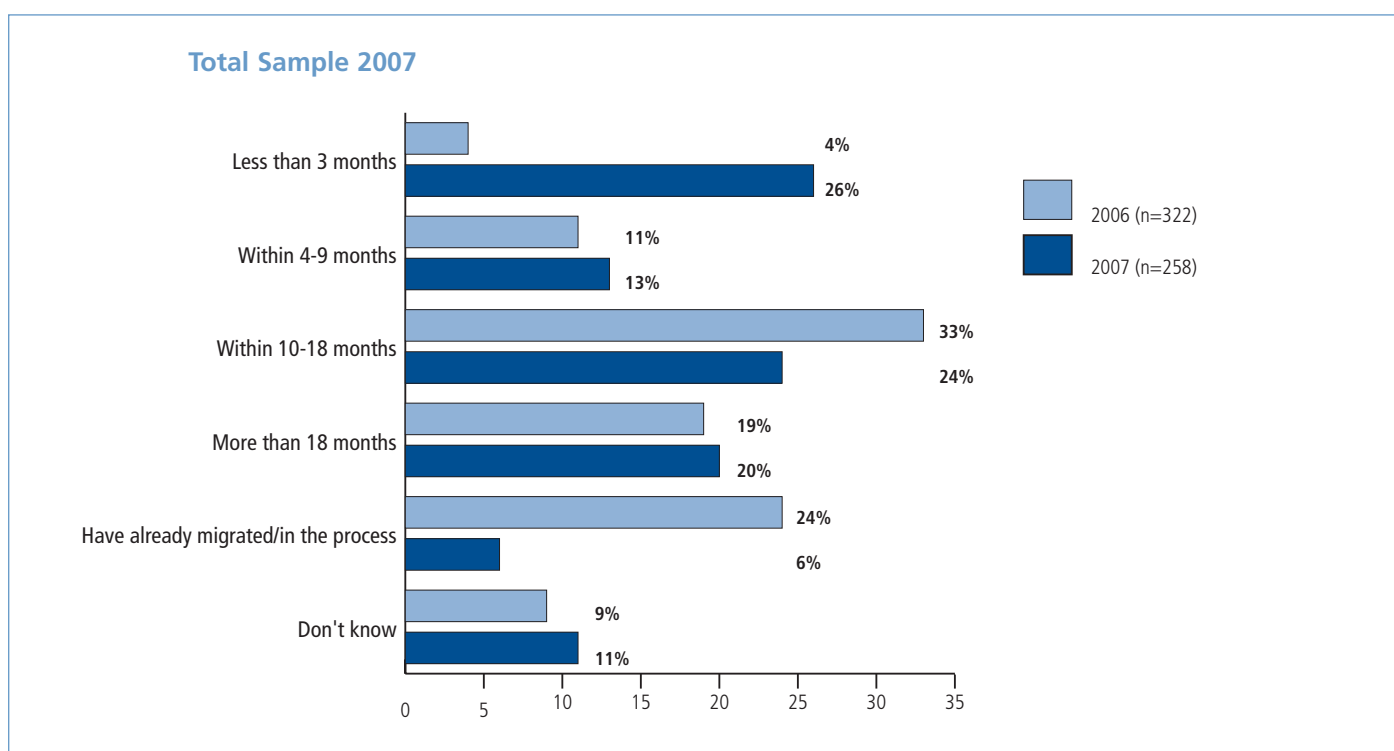
Electronic Common Technical Document (eCTD)

Three-fourths (76%) of respondents plan to migrate to the eCTD. Of those who do not plan to migrate to eCTD (n=23), their reasons include:

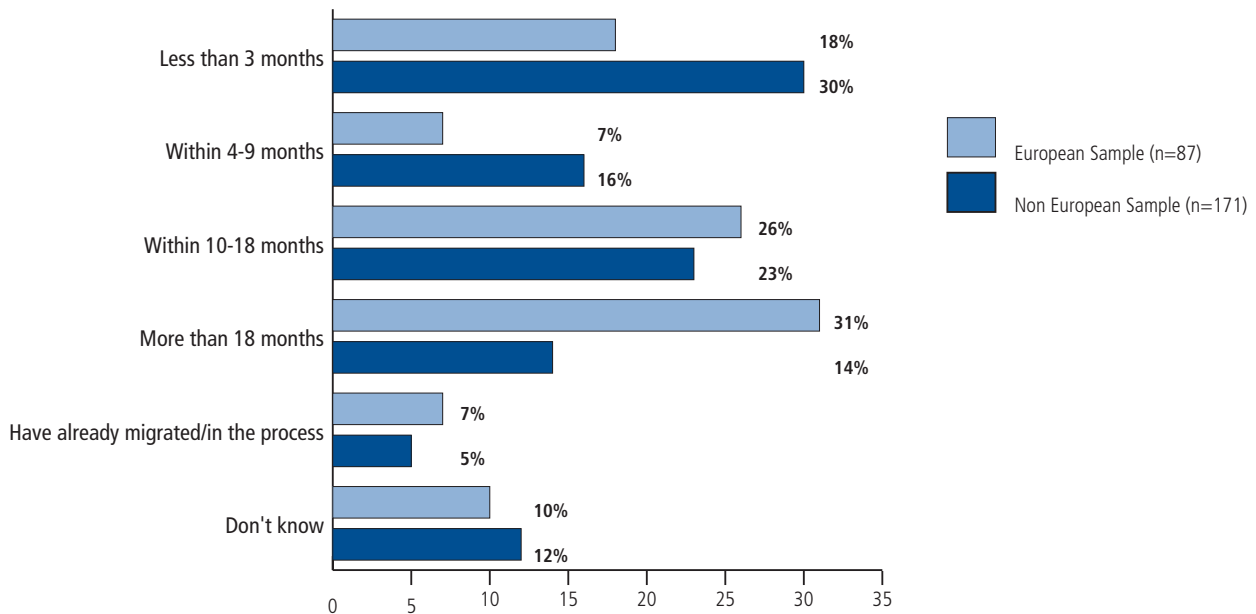
- Not applicable 56%
- Not essential or required 17%
- Other 22%
- Don't know 11%

One quarter (26%) of respondents plan to migrate to the eCTD within 3 months, significantly more than in 2006 (4%). Significantly fewer European respondents plan to migrate within 3 months, estimating the migration to be more than 18 months away.

Migration plans



European Sample 2007



Several of those planning to transition to eCTD expressed some concerns about it, as follows:

- Training level is inadequate / have no experience with it 12%*
- Small company / financial constraints 5%
- Lack of clear guidelines and direction 6%
- Other 22%

*Percentages based to n=80 respondents who answered this open-ended question.

Respondents also provided their thoughts on the impact that FDA changes to guidance will have on their transition to eCTD. Most felt the changes would have minimal or no impact on their movement to eCTD, or were not sure:

- Will accelerate our implementation / will happen sooner 8%*
- No impact — transition in process 8%
- Will have minimal impact 7%
- Not applicable / do not deal with FDA 7%
- Currently submit eCTDs 4%
- Waiting for more information 3%
- Impact is currently being discussed / analyzed 2%
- Will have significant (unspecified) impact 2%
- Will upgrade software / publishing tool 2%
- Not applicable — medical device company 2%
- Issue is U.S. colleagues' responsibility 1%
- Will delay implementation to eCTD 1%
- Aware but have not considered its impact 1%
- Other 6%
- No impact 21%
- Don't know/not sure 22%

*Percentages based to n=245 respondents who answered this open-ended question.

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The Thomson Corporation (www.thomson.com) is a global leader in providing essential electronic workflow solutions to business and professional customers. With operational headquarters in Stamford, Conn., Thomson provides value-added information, software tools and applications to professionals in the fields of law, tax, accounting, financial services, scientific research and healthcare. The Corporation's common shares are listed on the New York and Toronto stock exchanges (NYSE: TOC; TSX: TOC).



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