eTMF Exchange Mechanism Standard Survey
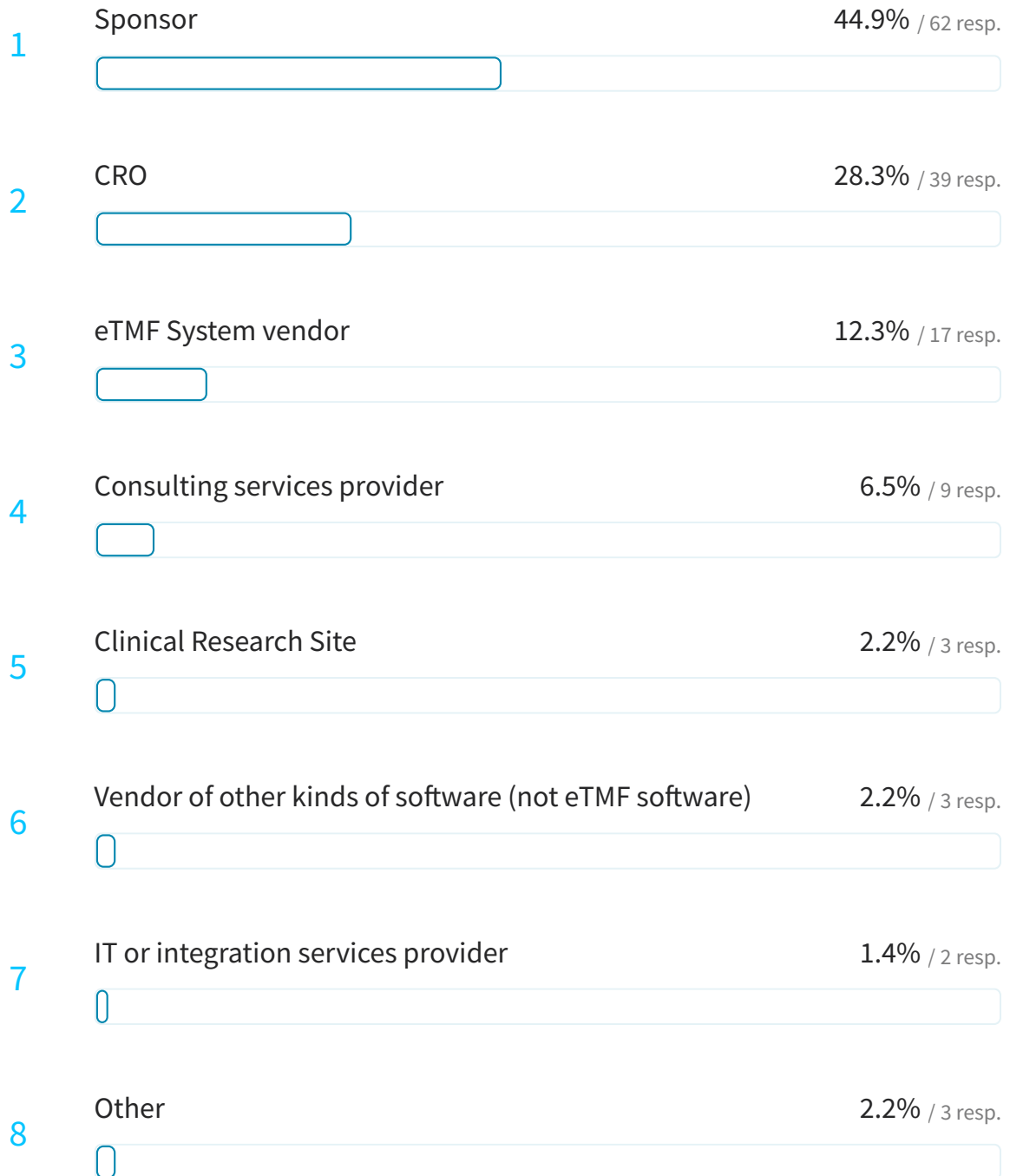
138 responses
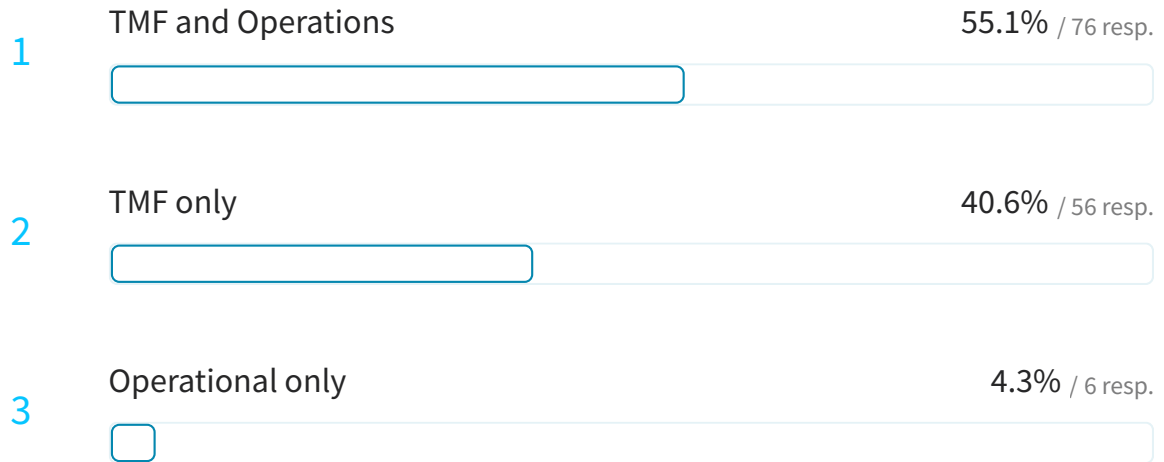
For what type of organization do you work?

138 out of 138 answered
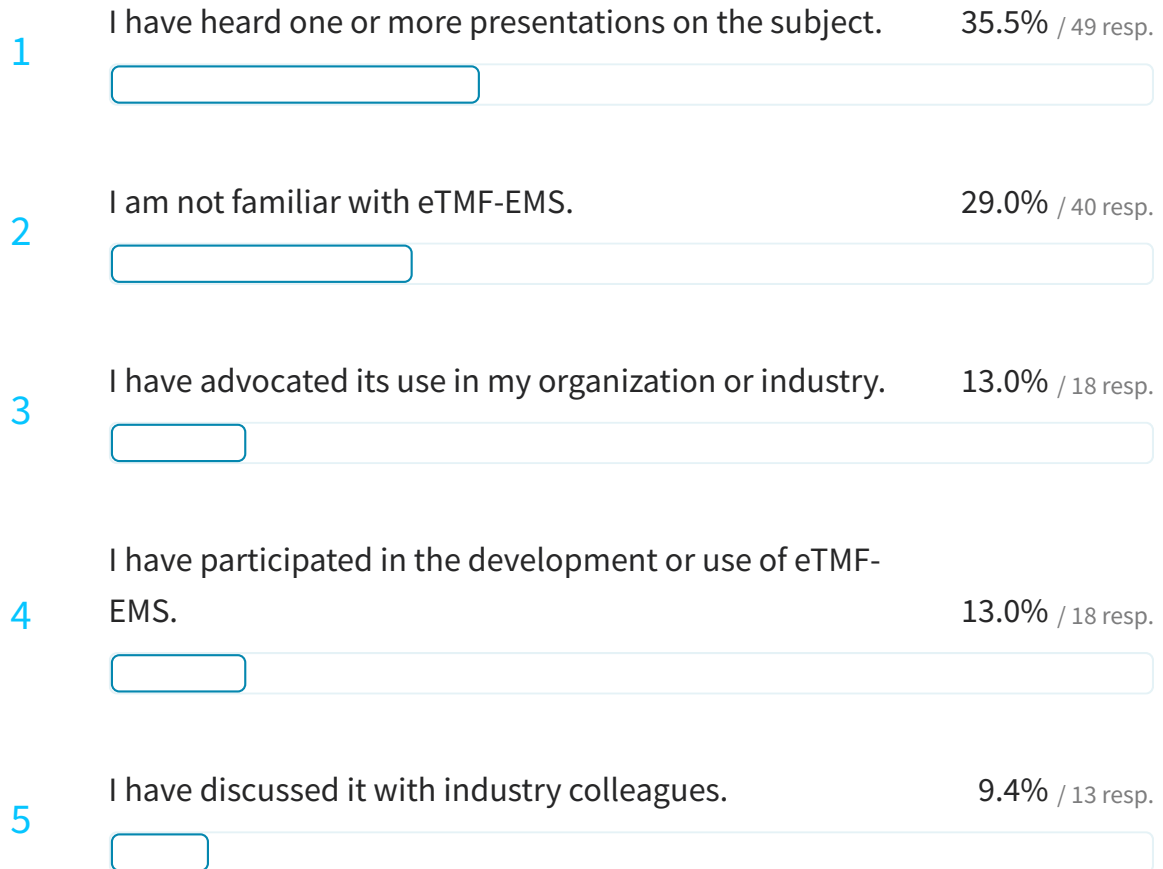
1	Sponsor	44.9% / 62 resp.

2	CRO	28.3% / 39 resp.

3	eTMF System vendor	12.3% / 17 resp.

4	Consulting services provider	6.5% / 9 resp.

5	Clinical Research Site	2.2% / 3 resp.

6	Vendor of other kinds of software (not eTMF software)	2.2% / 3 resp.

7	IT or integration services provider	1.4% / 2 resp.

8	Other	2.2% / 3 resp.

How does your role relate to TMF?

138 out of 138 answered

1   TMF and Operations   55.1% / 76 resp.

2   TMF only   40.6% / 56 resp.

3   Operational only   4.3% / 6 resp.

How familiar are you with eTMF-EMS?

138 out of 138 answered

1   I have heard one or more presentations on the subject.   35.5% / 49 resp.

2   I am not familiar with eTMF-EMS.   29.0% / 40 resp.

3   I have advocated its use in my organization or industry.   13.0% / 18 resp.

4   I have participated in the development or use of eTMF-EMS.   13.0% / 18 resp.

5   I have discussed it with industry colleagues.   9.4% / 13 resp.

Which of the following use cases would be of interest to you?

62 out of 138 answered

1   Transfer a final TMF from CRO to sponsor   64.5% / 40 resp.

2   Archive TMF content and metadata   51.6% / 32 resp.

3   Migrate TMF content after an acquisition   37.1% / 23 resp.

4   Transfer sponsor TMF content to and from a study site   29.0% / 18 resp.

5   Transfer interim TMF content to a central TMF   24.2% / 15 resp.

6   Transport records after upgrading an eTMF system   16.1% / 10 resp.

7   I have no specific use case in mind   6.5% / 4 resp.

8   Migrate TMF records to a new CRO   3.2% / 2 resp.

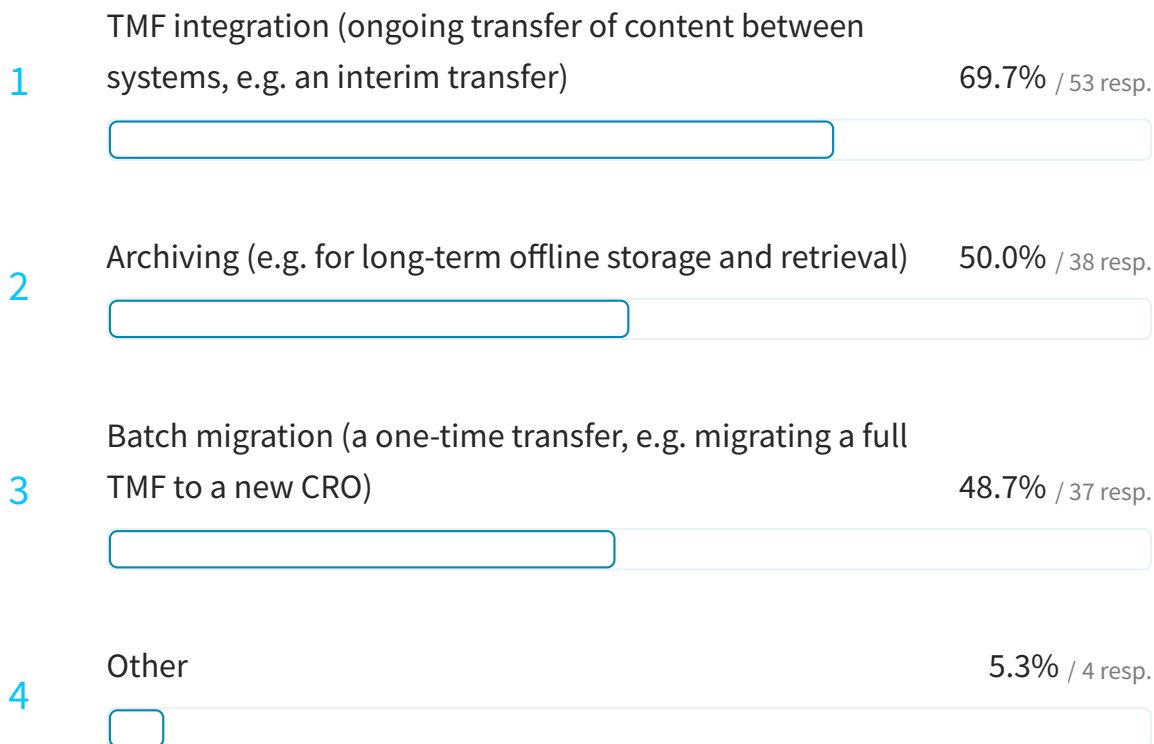9   Other   0.0% / 0 resp.

What would you say the biggest barriers are to using the EMS standard for TMF interchange? (check all that apply)

62 out of 138 answered

1 I don't know how to implement it   48.4% / 30 resp.

2 This is not a priority for us right now   29.0% / 18 resp.

3 We don't exchange TMF content and we have a
   centralized eTMF   17.7% / 11 resp.

4 My eTMF vendor does not yet support the standard   14.5% / 9 resp.

5 The cost of implementing is too high   12.9% / 8 resp.

6 Standard is not comprehensive enough   8.1% / 5 resp.

7 We already have a mechanism for exchanging content that
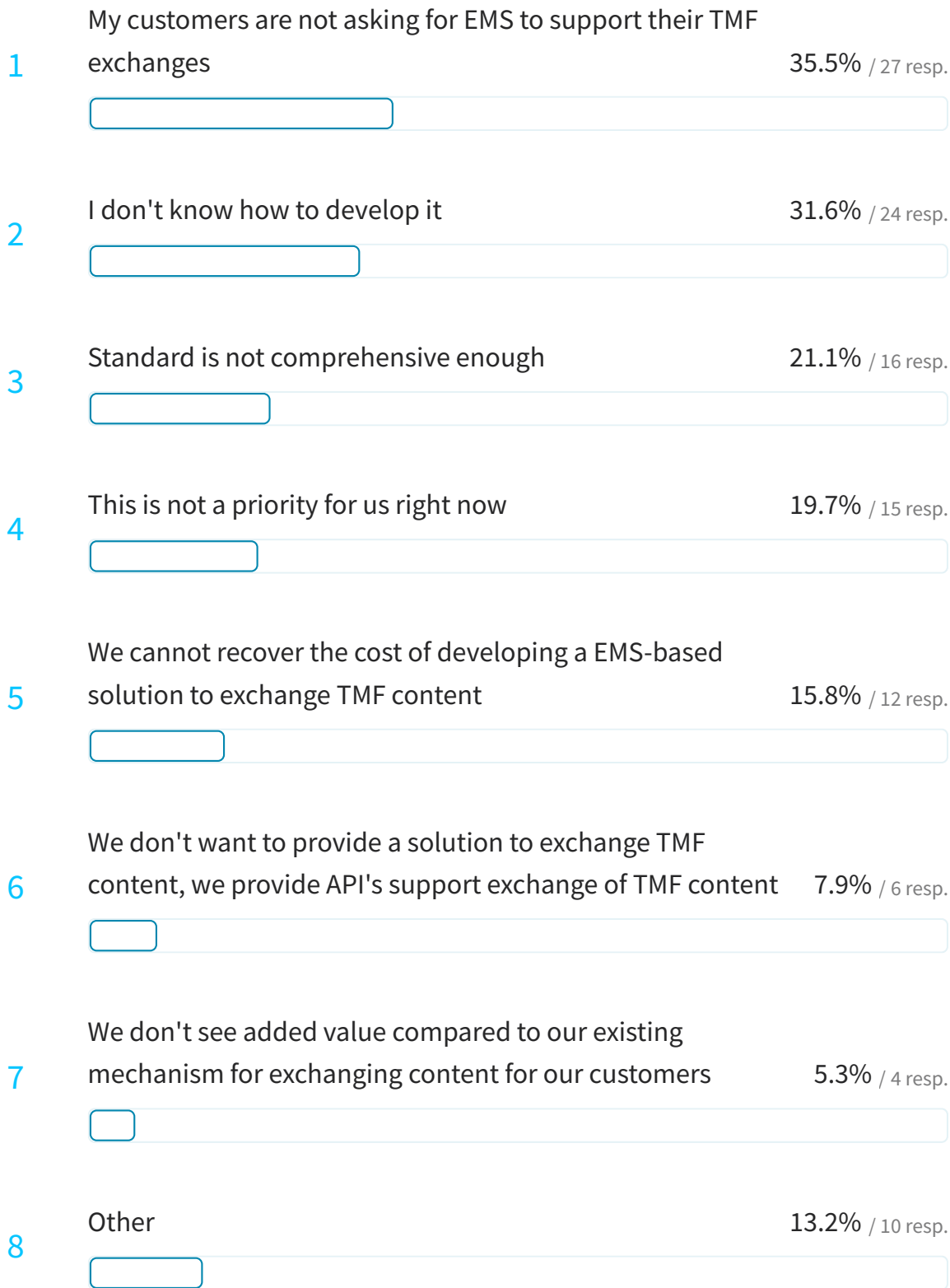   works fine   3.2% / 2 resp.

8 Other   8.1% / 5 resp.

Which of the following TMF exchange solution types do you (partial or fully) support?
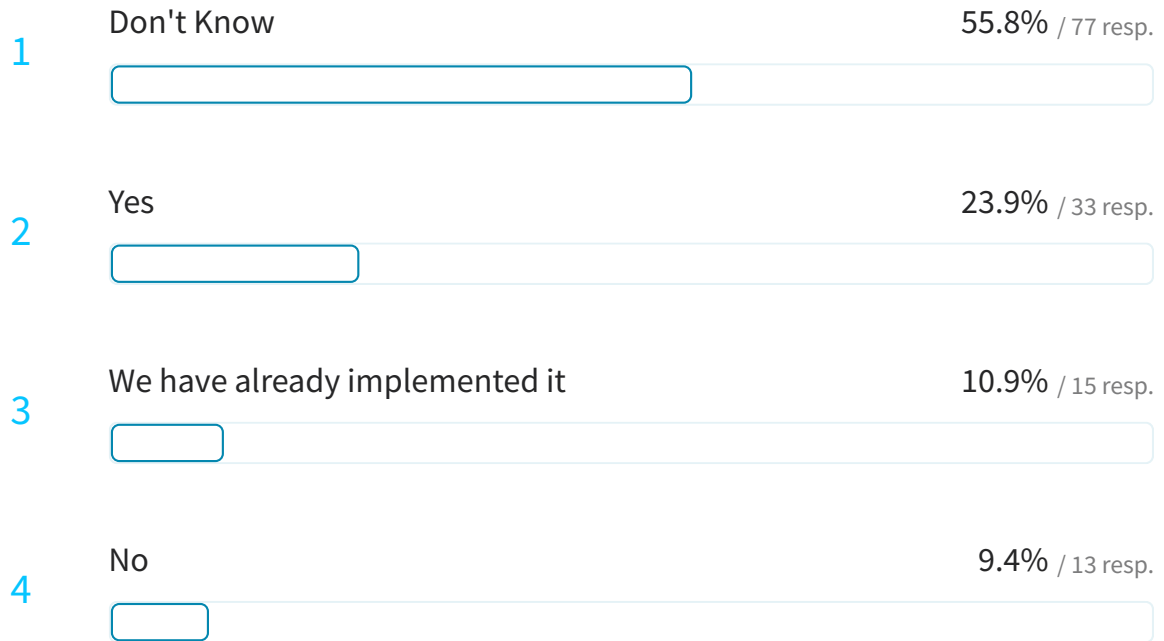
76 out of 138 answered

1   TMF integration (ongoing transfer of content between systems, e.g. an interim transfer)   69.7% / 53 resp.

2   Archiving (e.g. for long-term offline storage and retrieval)   50.0% / 38 resp.

3   Batch migration (a one-time transfer, e.g. migrating a full TMF to a new CRO)   48.7% / 37 resp.

4   Other   5.3% / 4 resp.

What would you say are the biggest barriers to developing the EMS standard for TMF interchange? (check all that apply)
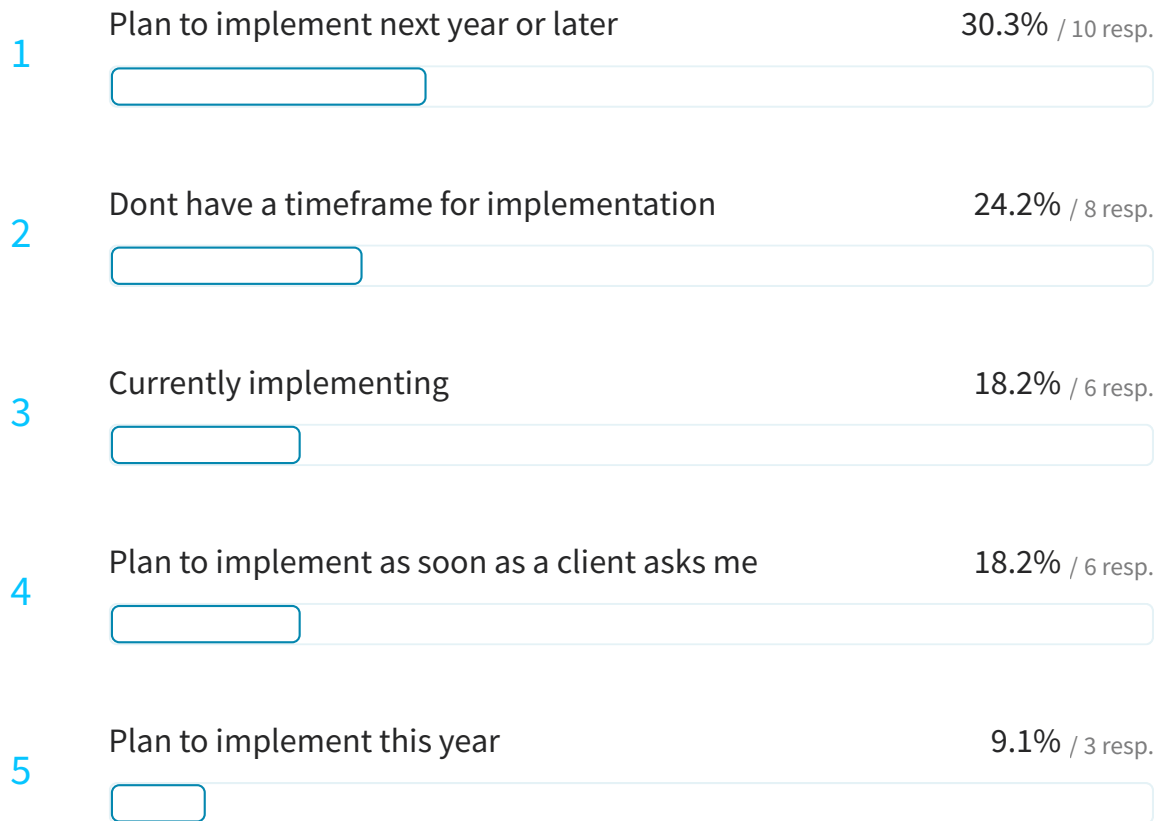
76 out of 138 answered

1 My customers are not asking for EMS to support their TMF exchanges

35.5% / 27 resp.

2 I don't know how to develop it

31.6% / 24 resp.

3 Standard is not comprehensive enough

21.1% / 16 resp.

4 This is not a priority for us right now

19.7% / 15 resp.

5 We cannot recover the cost of developing a EMS-based solution to exchange TMF content

15.8% / 12 resp.

6 We don't want to provide a solution to exchange TMF content, we provide API's support exchange of TMF content

7.9% / 6 resp.

7 We don't see added value compared to our existing mechanism for exchanging content for our customers

5.3% / 4 resp.

8 Other

13.2% / 10 resp.

Do you plan on (partial or fully) implementing the eTMF-EMS?

138 out of 138 answered

1   Don't Know   55.8% / 77 resp.

2   Yes   23.9% / 33 resp.

3   We have already implemented it   10.9% / 15 resp.

4   No   9.4% / 13 resp.

If you have not implemented the EMS, what is your timeframe for implementation?

33 out of 138 answered

1   Plan to implement next year or later   30.3% / 10 resp.

2   Dont have a timeframe for implementation   24.2% / 8 resp.

3   Currently implementing   18.2% / 6 resp.

4   Plan to implement as soon as a client asks me   18.2% / 6 resp.

5   Plan to implement this year   9.1% / 3 resp.

What would be the overall value to your organization if you were to use the eTMF-EMS to transfer interim TMF content?

15 out of 138 answered
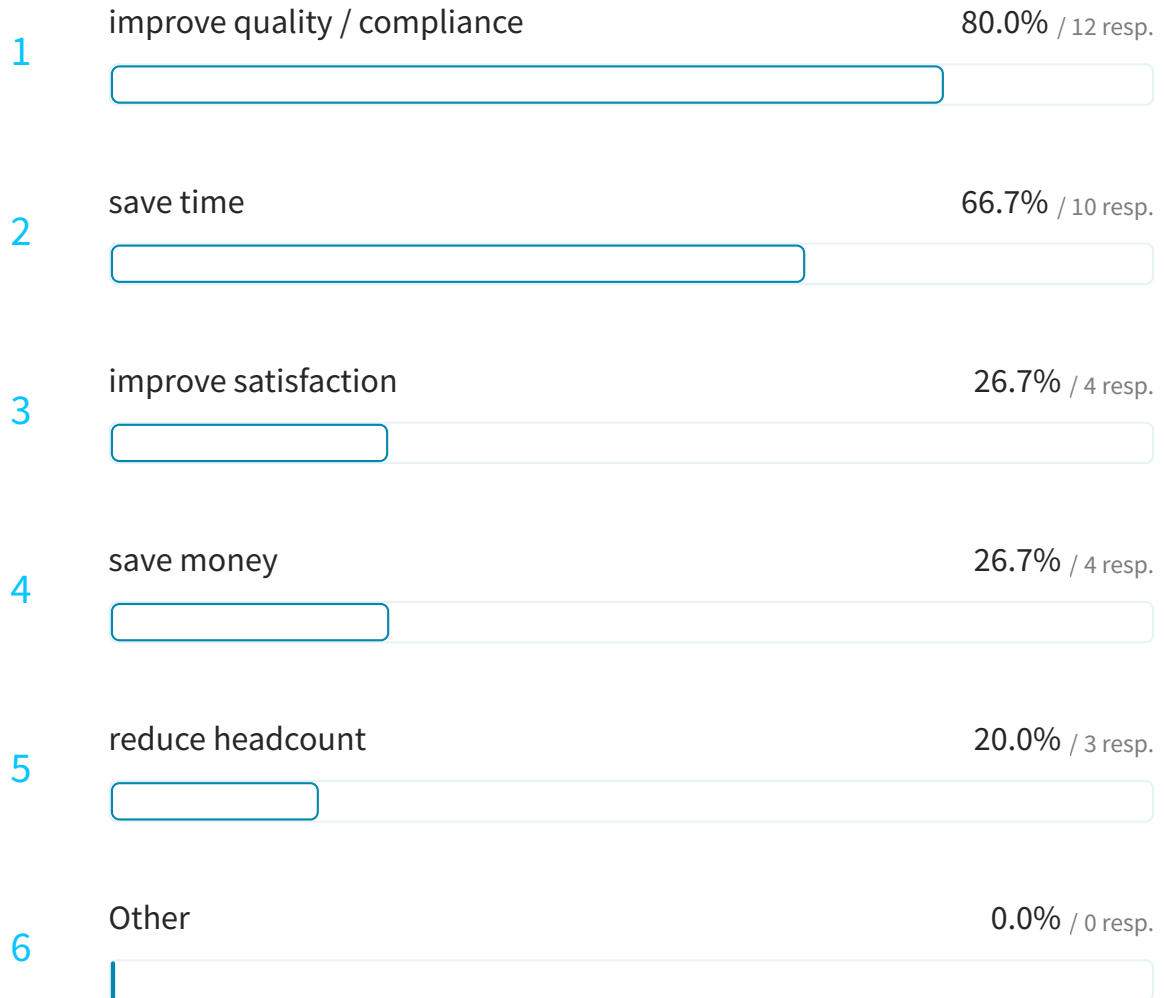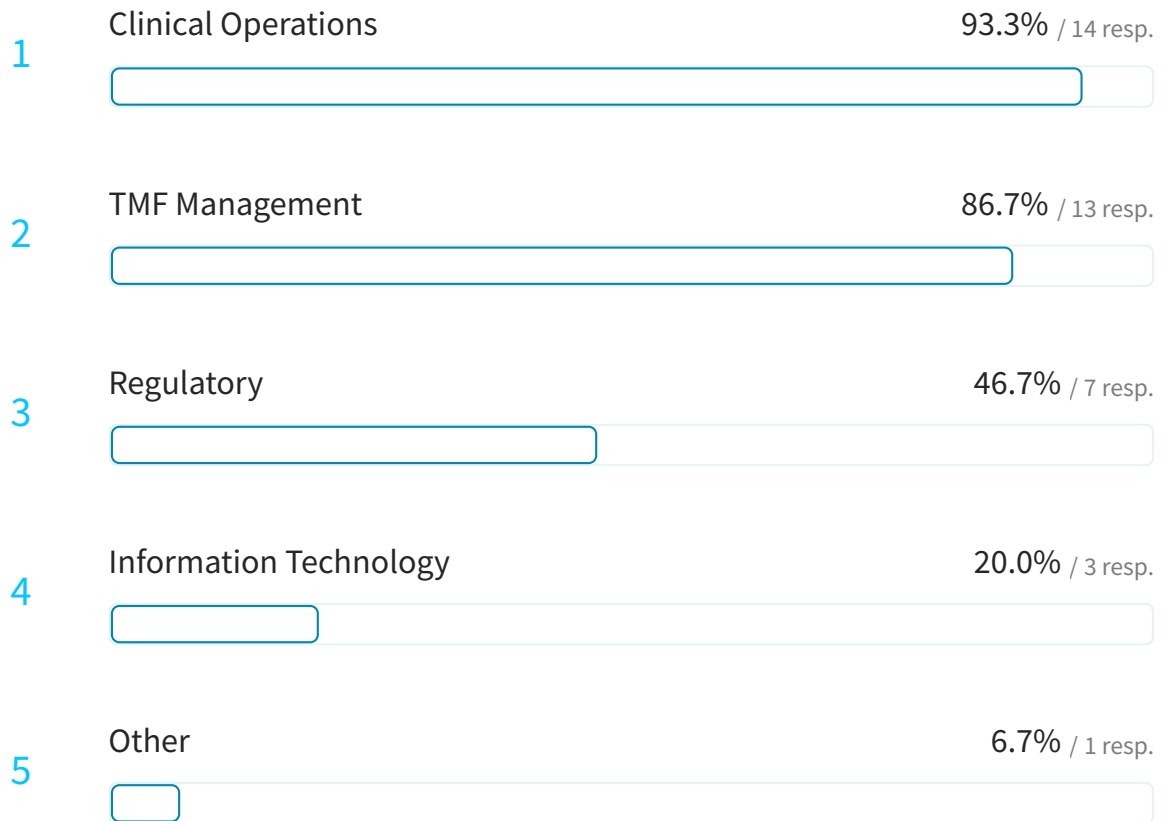
3.7 Average rating

6.7%	13.3%	20.0%	26.7%	33.3%
1 resp.	2 resp.	3 resp.	4 resp.	5 resp.
1	2	3	4	5

Least Value   Most Value
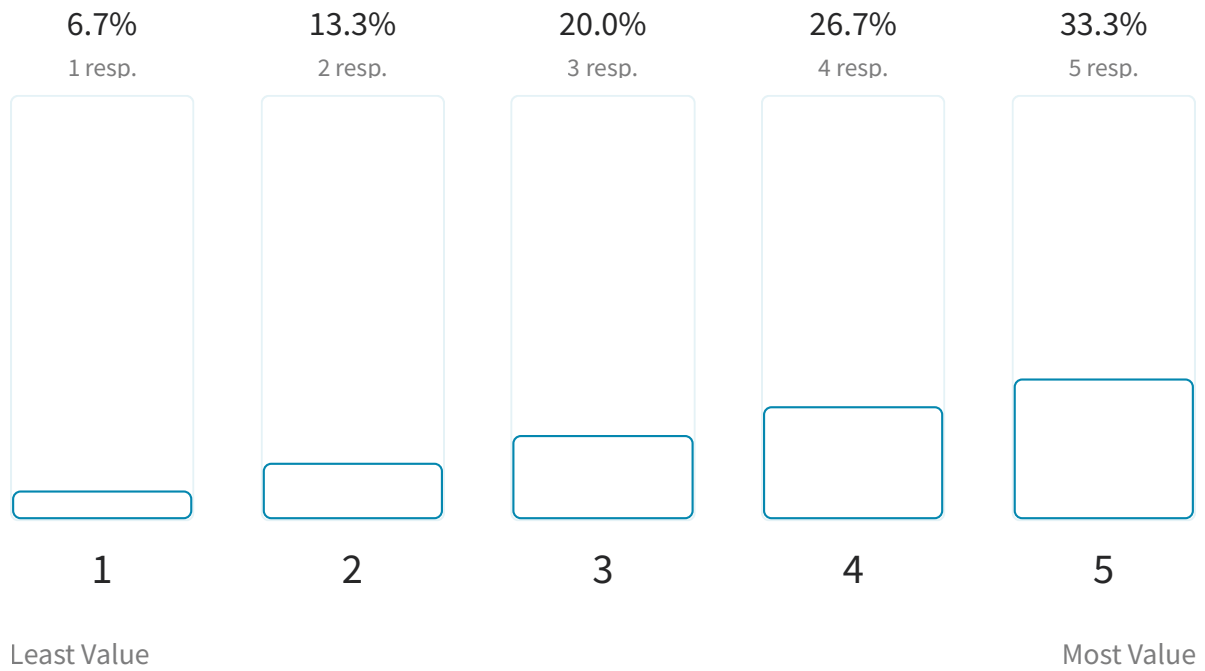
What specific value would this use case bring to your organization?

15 out of 138 answered

1	improve quality / compliance	80.0% / 12 resp.
2	save time	66.7% / 10 resp.
3	improve satisfaction	26.7% / 4 resp.
4	save money	26.7% / 4 resp.
5	reduce headcount	20.0% / 3 resp.
6	Other	0.0% / 0 resp.

Which part(s) of the organization would gain business value for this use case?

15 out of 138 answered

1   Clinical Operations   93.3% / 14 resp.

2   TMF Management   86.7% / 13 resp.

3   Regulatory   46.7% / 7 resp.

4   Information Technology   20.0% / 3 resp.

5   Other   6.7% / 1 resp.

Who is the decision-maker for implementing a solution for this use case?

15 out of 138 answered

1   Senior management / leadership   80.0% / 12 resp.

2   TMF Management   46.7% / 7 resp.

3   Information Technology   26.7% / 4 resp.

4   Clinical Operations   20.0% / 3 resp.

5   Regulatory   6.7% / 1 resp.

6   Other   0.0% / 0 resp.

How do you currently do interim transfers of TMF content?

15 out of 138 answered

1 CRO sends content via email and sponsor uploads it into eTMF 33.3% / 5 resp.

2 CRO uploads content into the sponsor eTMF manually 33.3% / 5 resp.

3 We don't do interim transfers 33.3% / 5 resp.

4 We have an integration with the destination system 20.0% / 3 resp.

5 Other 0.0% / 0 resp.

How critical would this use case be to the selection of an eTMF system or CRO?

15 out of 138 answered

3.3 Average rating
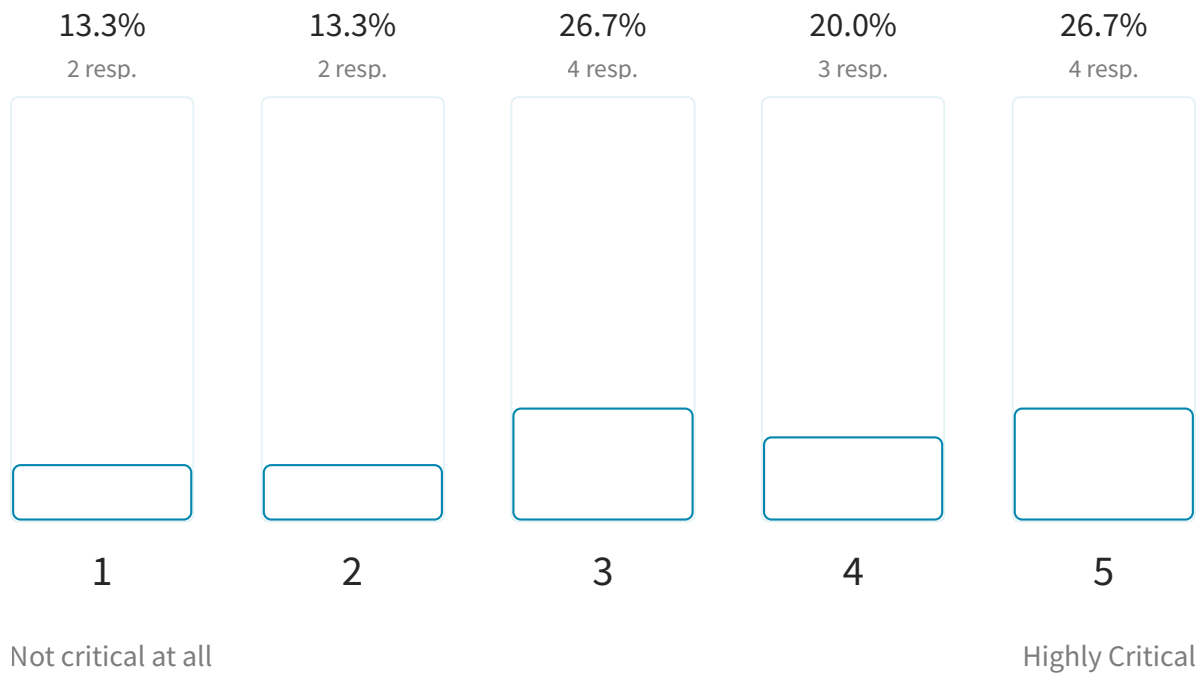
13.3%	13.3%	26.7%	20.0%	26.7%
2 resp.	2 resp.	4 resp.	3 resp.	4 resp.
1	2	3	4	5

Not critical at all   Highly Critical

...What would be the overall value to your organization if you were to use the eTMF-EMS to migrate TMF records to a new CRO?

2 out of 138 answered
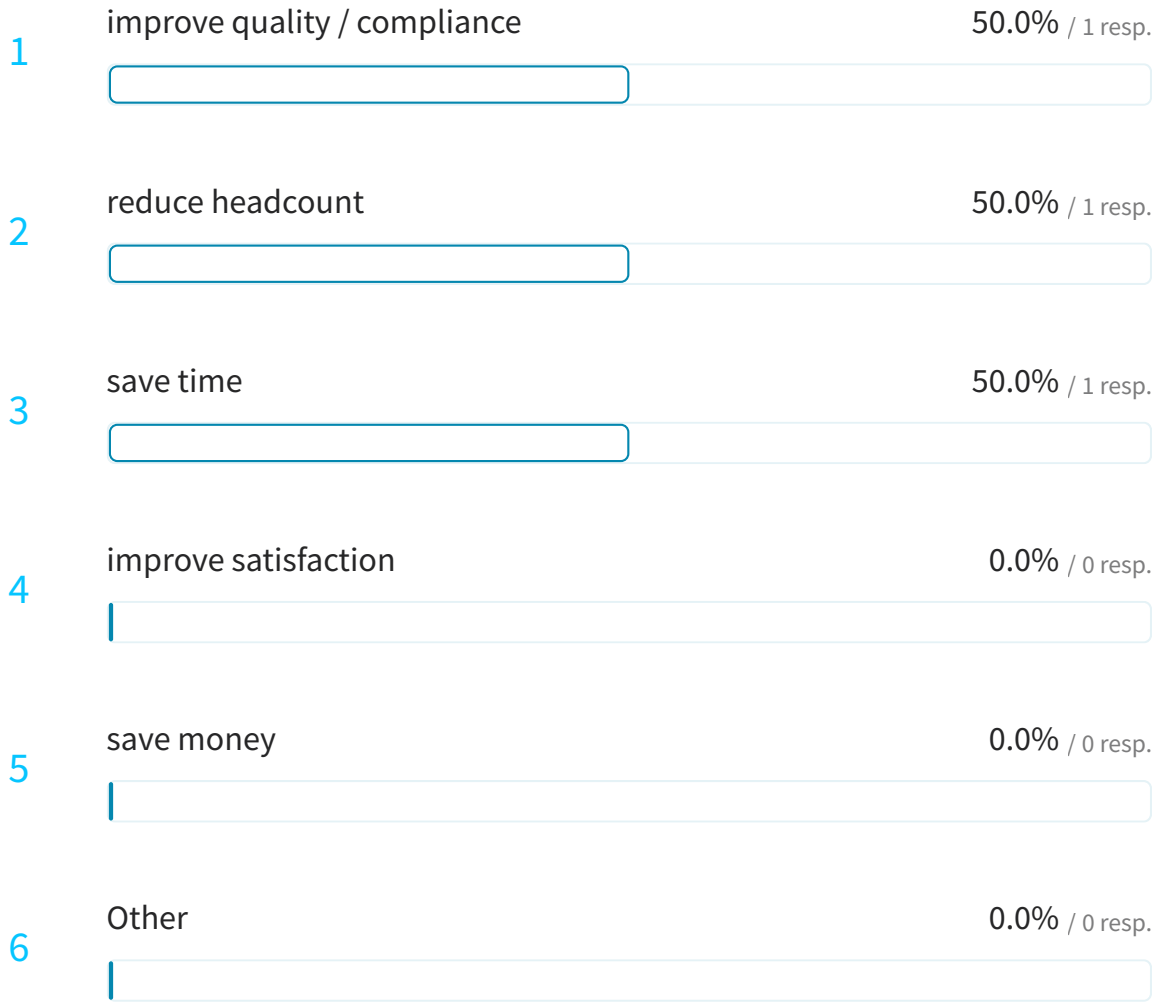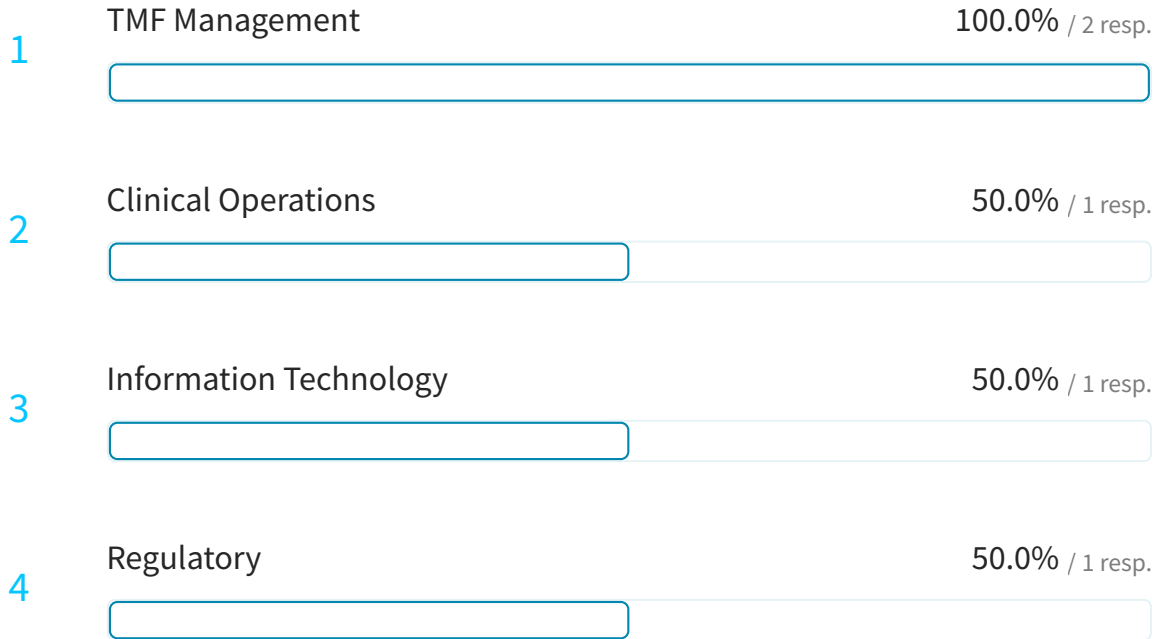
4.0 Average rating

0.0%	0.0%	0.0%	100.0%	0.0%
0 resp.	0 resp.	0 resp.	2 resp.	0 resp.
1	2	3	4	5

Least Value   Most Value
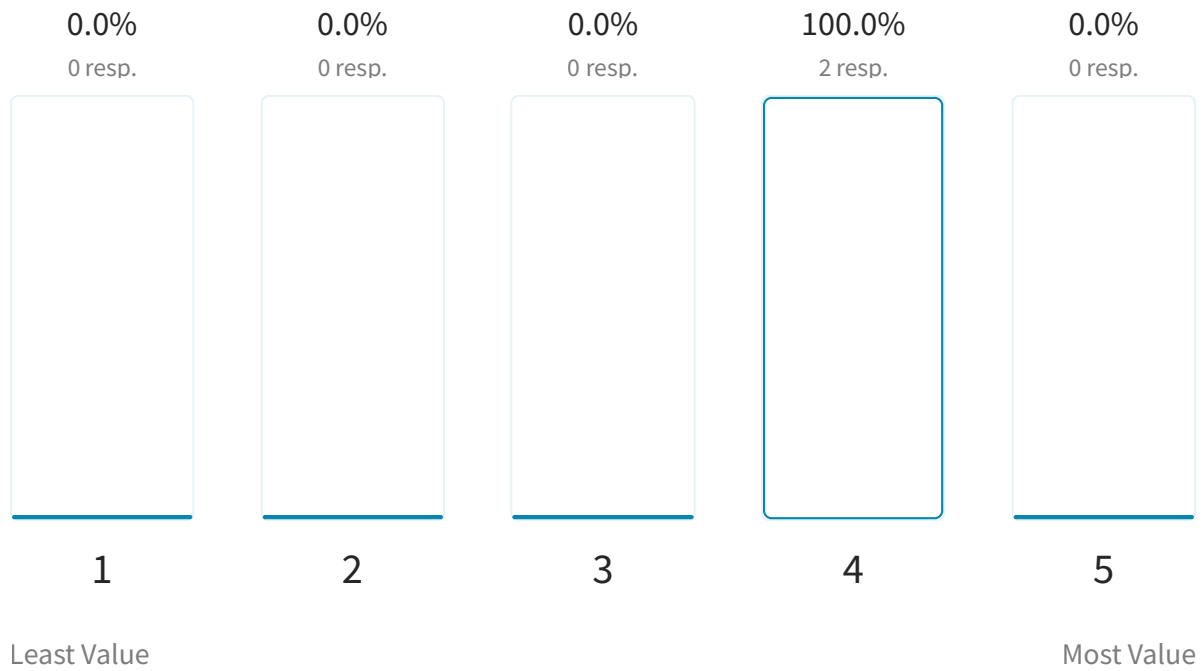
What specific value would this use case bring to your organization?

2 out of 138 answered

1 improve quality / compliance   50.0% / 1 resp.

2 reduce headcount   50.0% / 1 resp.

3 save time   50.0% / 1 resp.

4 improve satisfaction   0.0% / 0 resp.

5 save money   0.0% / 0 resp.

6 Other   0.0% / 0 resp.

Which part(s) of the organization would gain business value for this use case?

2 out of 138 answered

1   TMF Management   100.0% / 2 resp.

2   Clinical Operations   50.0% / 1 resp.

3   Information Technology   50.0% / 1 resp.

4   Regulatory   50.0% / 1 resp.

Who is the decision-maker for implementing a solution for this use case?

2 out of 138 answered

1   Senior management / leadership   50.0% / 1 resp.

2   TMF Management   50.0% / 1 resp.

3   Clinical Operations   0.0% / 0 resp.

4   Information Technology   0.0% / 0 resp.

5   Regulatory   0.0% / 0 resp.

6   Other   0.0% / 0 resp.
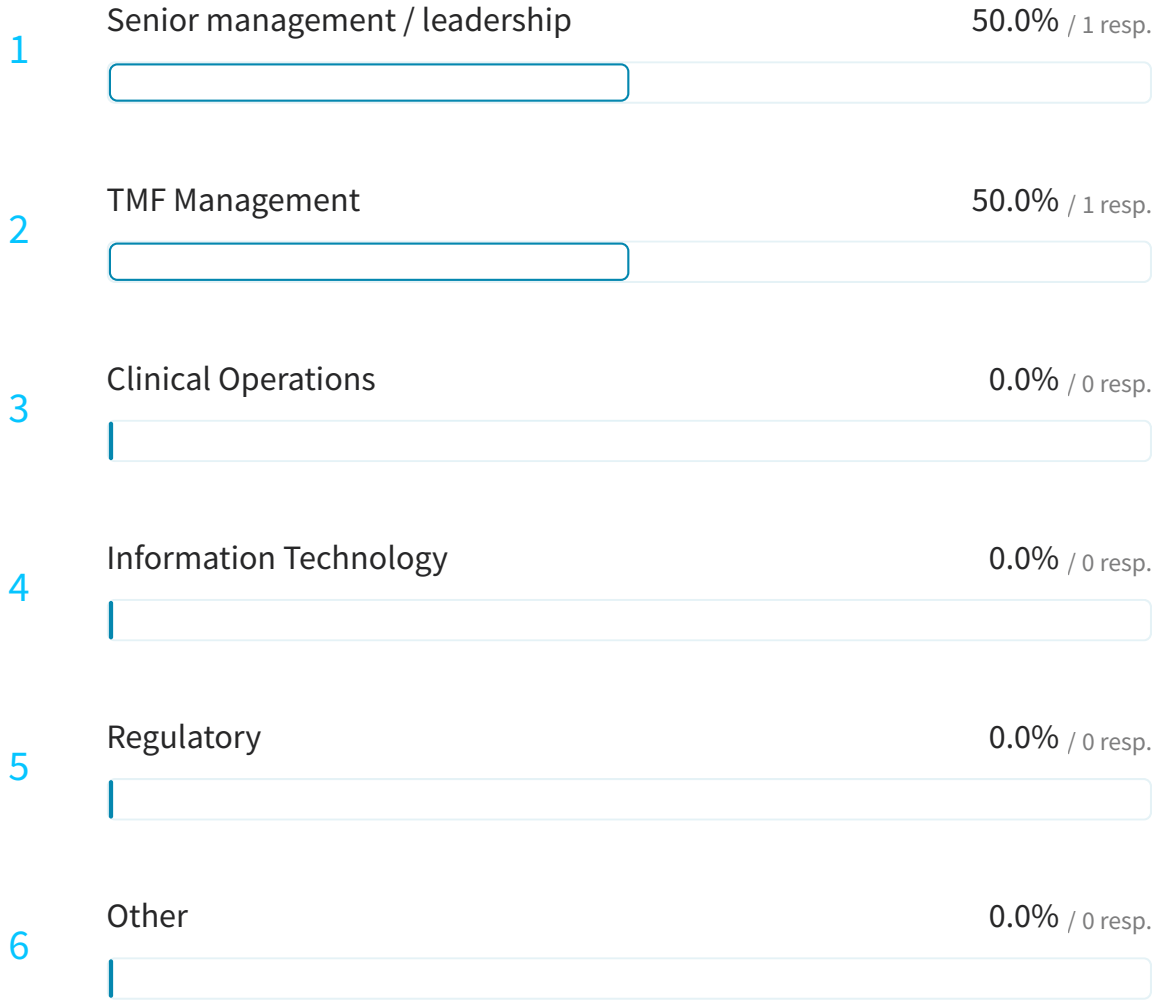
How do you currently migrate TMF records to a new CRO?

2 out of 138 answered

1   We extract the records into a folder structure based on the
     TMF Reference Model with an Excel file containing all of
     the metadata   50.0% / 1 resp.

2   We typically provide paper records to the CRO   50.0% / 1 resp.

3   Don't know   0.0% / 0 resp.

4   We extract the records into a folder structure based on our
     own filing structure with an Excel file containing all of the
     metadata   0.0% / 0 resp.

5   We send electronic files via email   0.0% / 0 resp.

6   We upload records and metadata directly into the CROs
     eTMF system   0.0% / 0 resp.

7   Other   0.0% / 0 resp.

How critical would this use case be to the selection of an eTMF system or CRO?
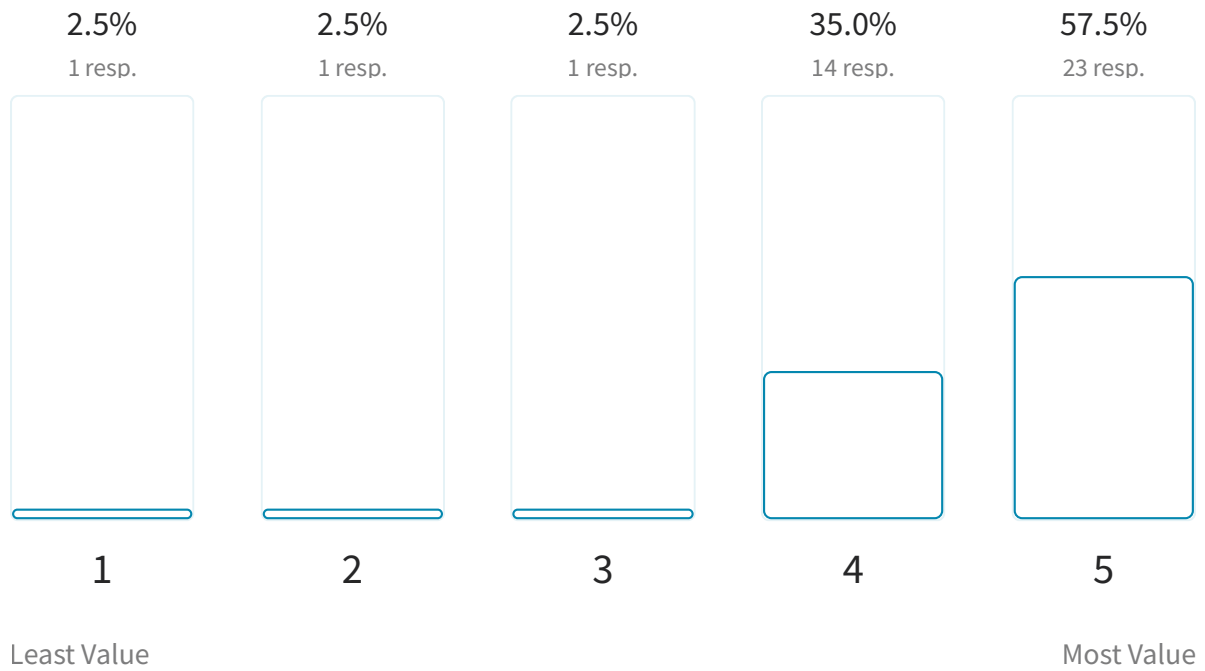
2 out of 138 answered
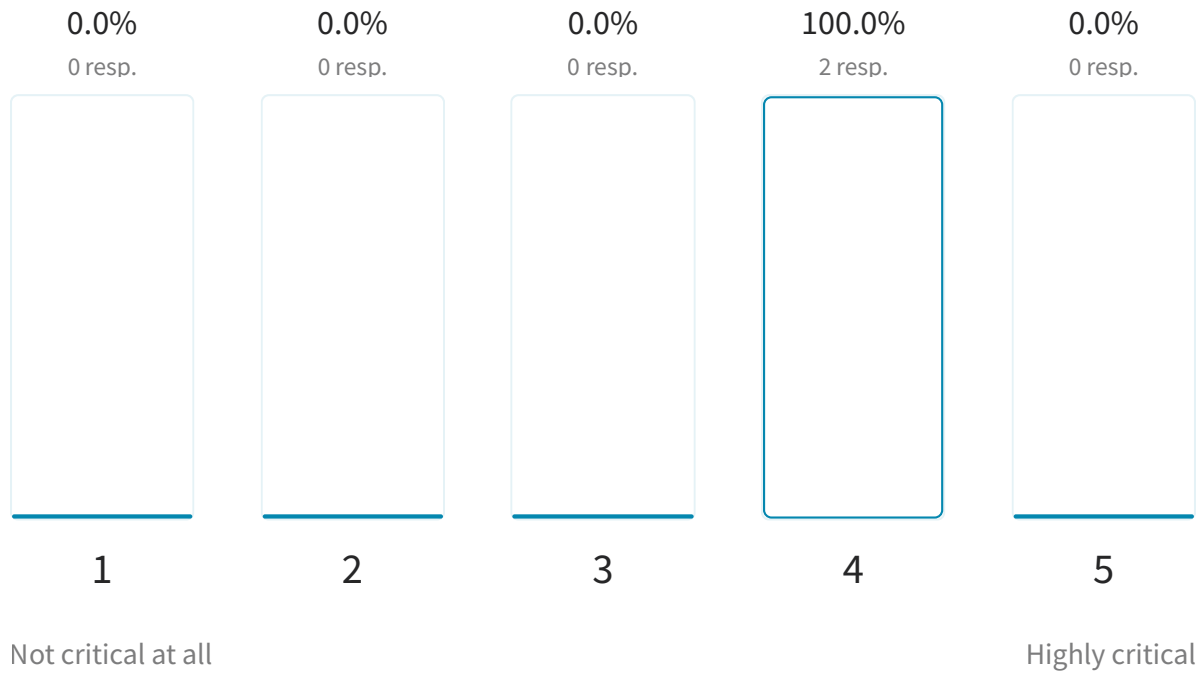
4.0 Average rating

0.0%	0.0%	0.0%	100.0%	0.0%
0 resp.	0 resp.	0 resp.	2 resp.	0 resp.
1	2	3	4	5

Not critical at all   Highly critical

What would be the overall value to your organization if you were to use the eTMF-EMS to transfer final TMF content from CRO to Sponsor?
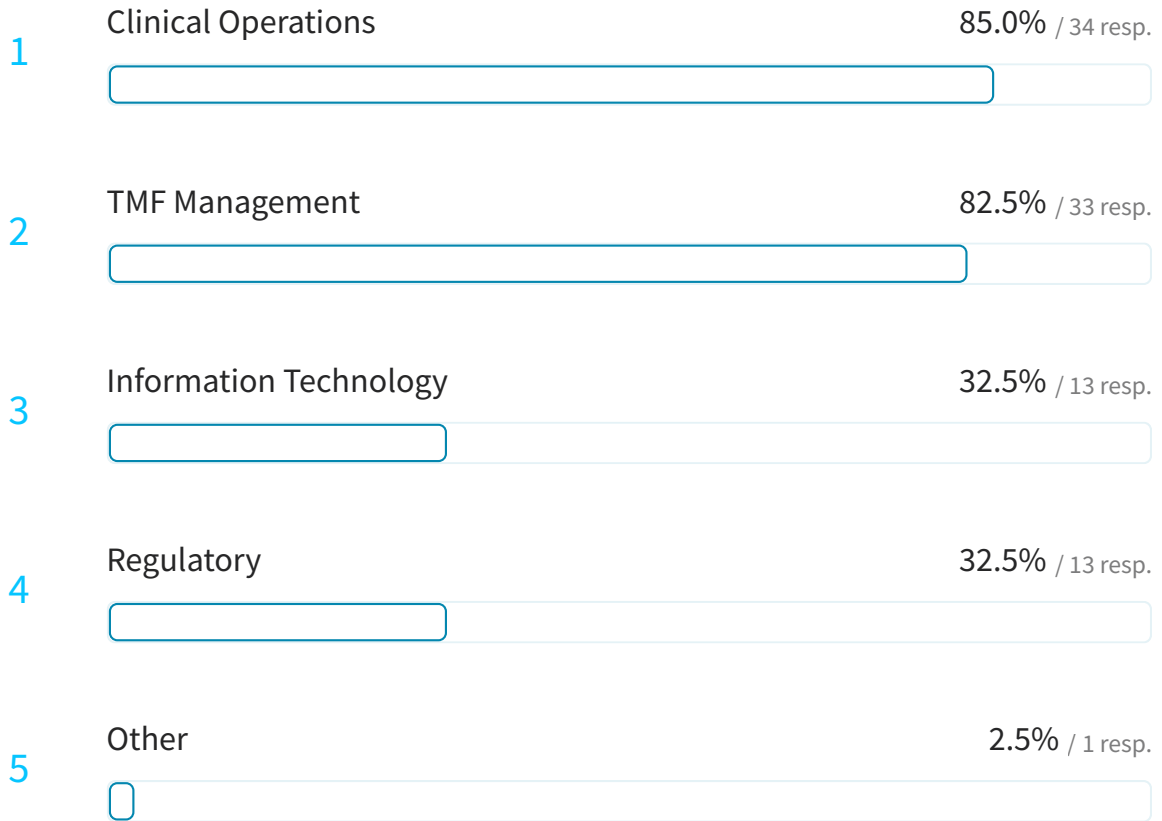
40 out of 138 answered

4.4 Average rating

2.5%	2.5%	2.5%	35.0%	57.5%
1 resp.	1 resp.	1 resp.	14 resp.	23 resp.
1	2	3	4	5

Least Value　　　　　　　　　　　　　　　　　　　　　　　　　　Most Value

What specific value would this use case bring to your organization?

40 out of 138 answered
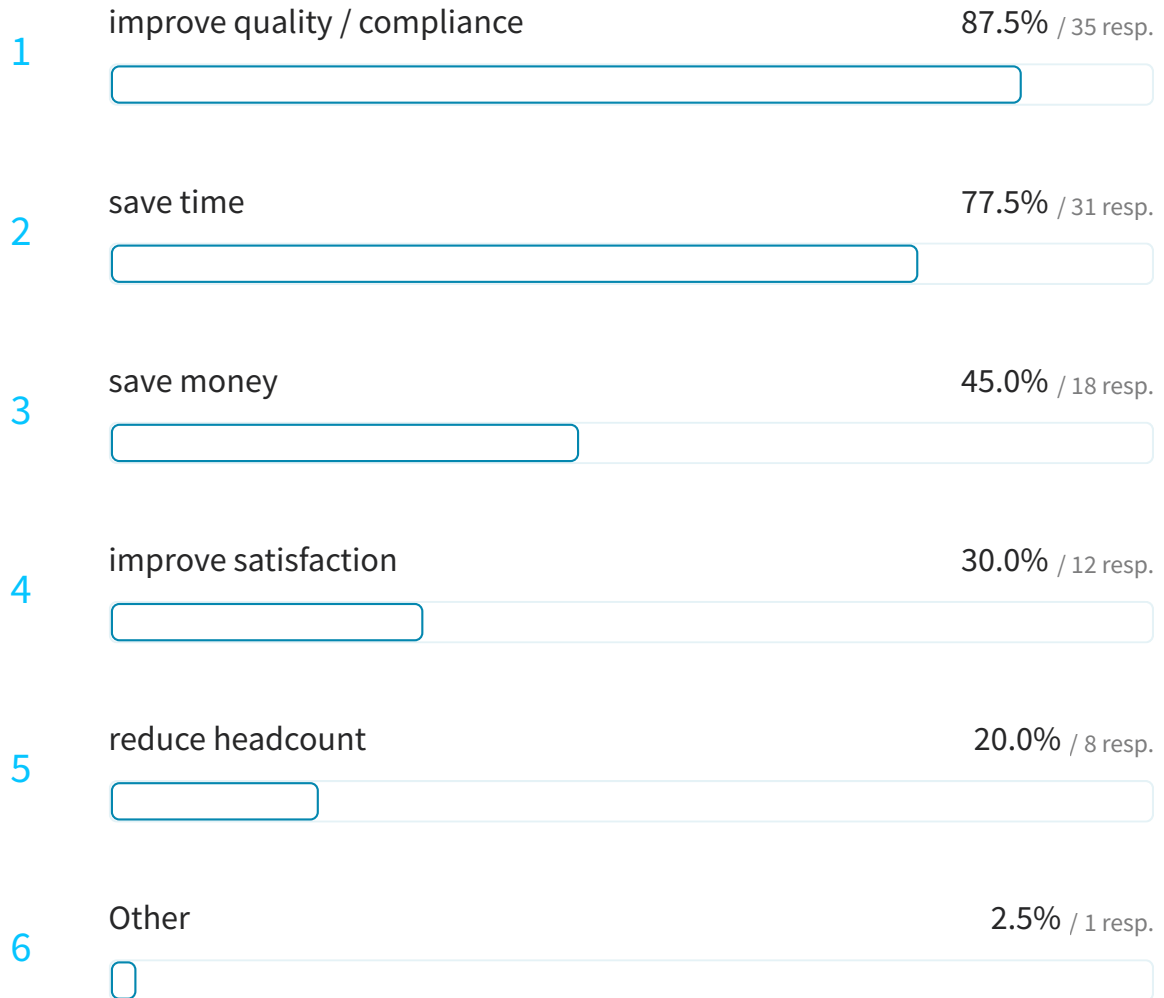
1   improve quality / compliance   87.5% / 35 resp.

2   save time   77.5% / 31 resp.

3   save money   45.0% / 18 resp.

4   improve satisfaction   30.0% / 12 resp.

5   reduce headcount   20.0% / 8 resp.

6   Other   2.5% / 1 resp.

Which part(s) of the organization would gain business value for this use case?

40 out of 138 answered

1   Clinical Operations   85.0% / 34 resp.

2   TMF Management   82.5% / 33 resp.

3   Information Technology   32.5% / 13 resp.

4   Regulatory   32.5% / 13 resp.

5   Other   2.5% / 1 resp.

Who is the decision-maker for implementing a solution for this use case?

40 out of 138 answered

1   Senior management / leadership   72.5% / 29 resp.

2   Clinical Operations   37.5% / 15 resp.

3   TMF Management   37.5% / 15 resp.

4   Information Technology   30.0% / 12 resp.

5   Regulatory   5.0% / 2 resp.

6   Other   0.0% / 0 resp.
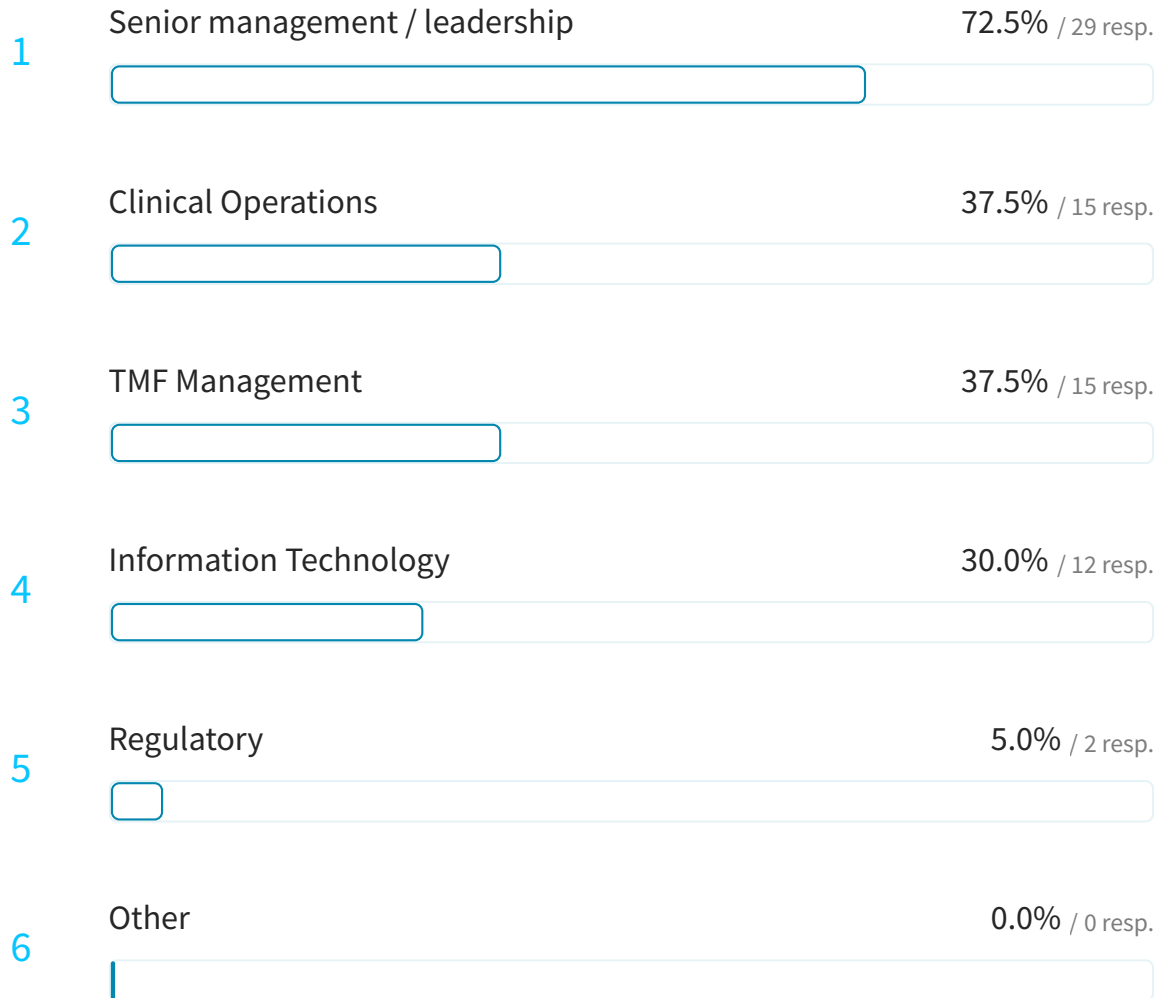
How are final transfers of the eTMF from CRO to Sponsor currently performed?

40 out of 138 answered

1   CRO sends content by file transfer and sponsor enters
     content manually into eTMF   52.5% / 21 resp.

2   CRO enters content manually into Sponsor eTMF   20.0% / 8 resp.

3   Content is automatically transferred via an integration
     between CRO and sponsor   15.0% / 6 resp.

4   Other   22.5% / 9 resp.
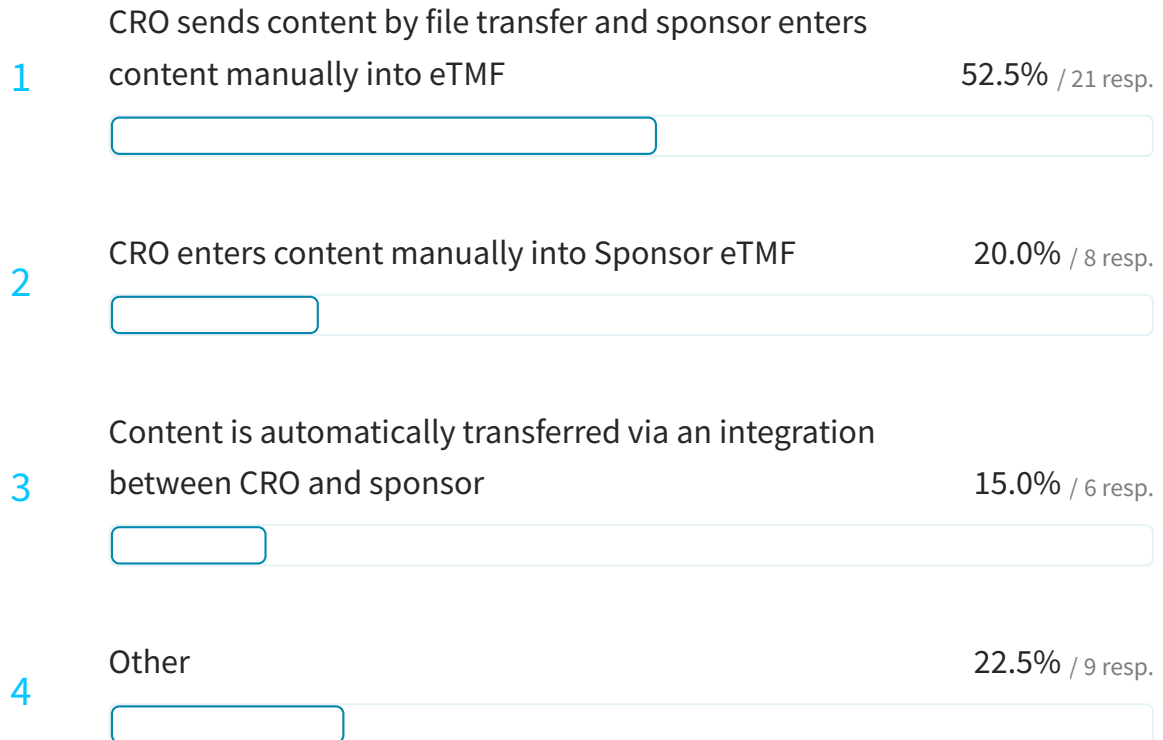
How critical would this use case be to the selection of an eTMF system or CRO?

40 out of 138 answered

3.5 Average rating

7.5%	2.5%	40.0%	30.0%	20.0%
3 resp.	1 resp.	16 resp.	12 resp.	8 resp.
1	2	3	4	5

Not critical at all   Highly Critical
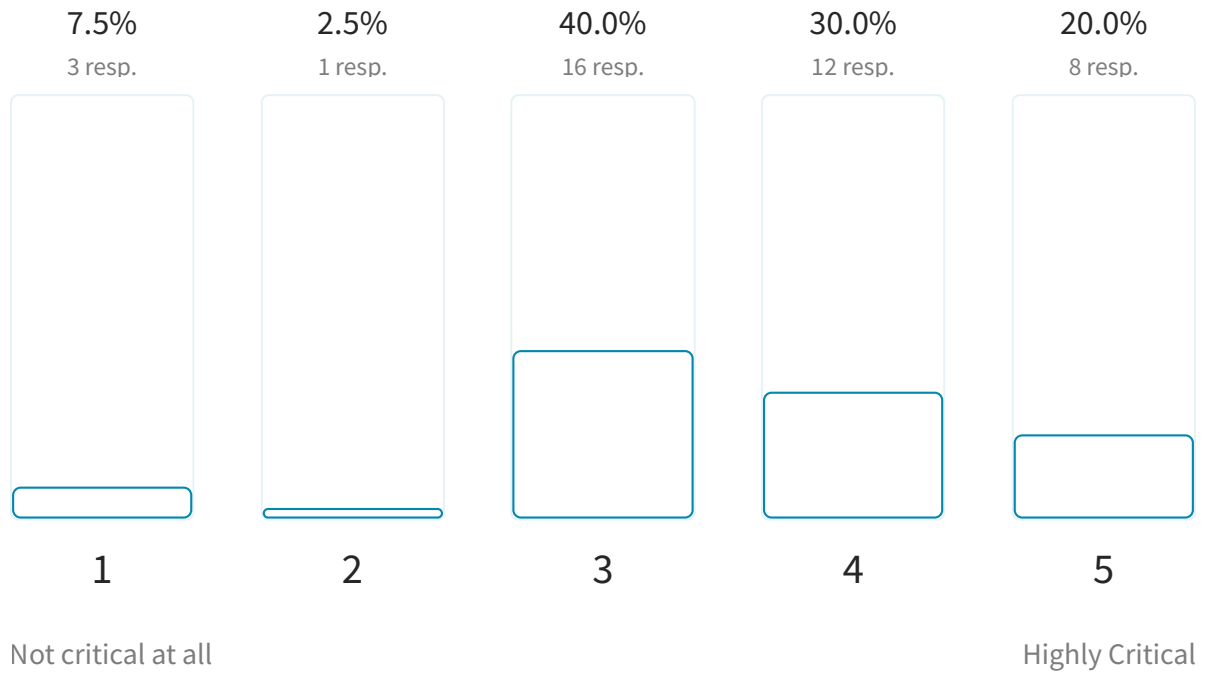
What would be the overall value to your organization if you were to use the eTMF-EMS to archive TMF content and metadata?

32 out of 138 answered

4.2 Average rating

0.0%	0.0%	15.6%	46.9%	37.5%
0 resp.	0 resp.	5 resp.	15 resp.	12 resp.

1	2	3	4	5

Least Value   Most Value
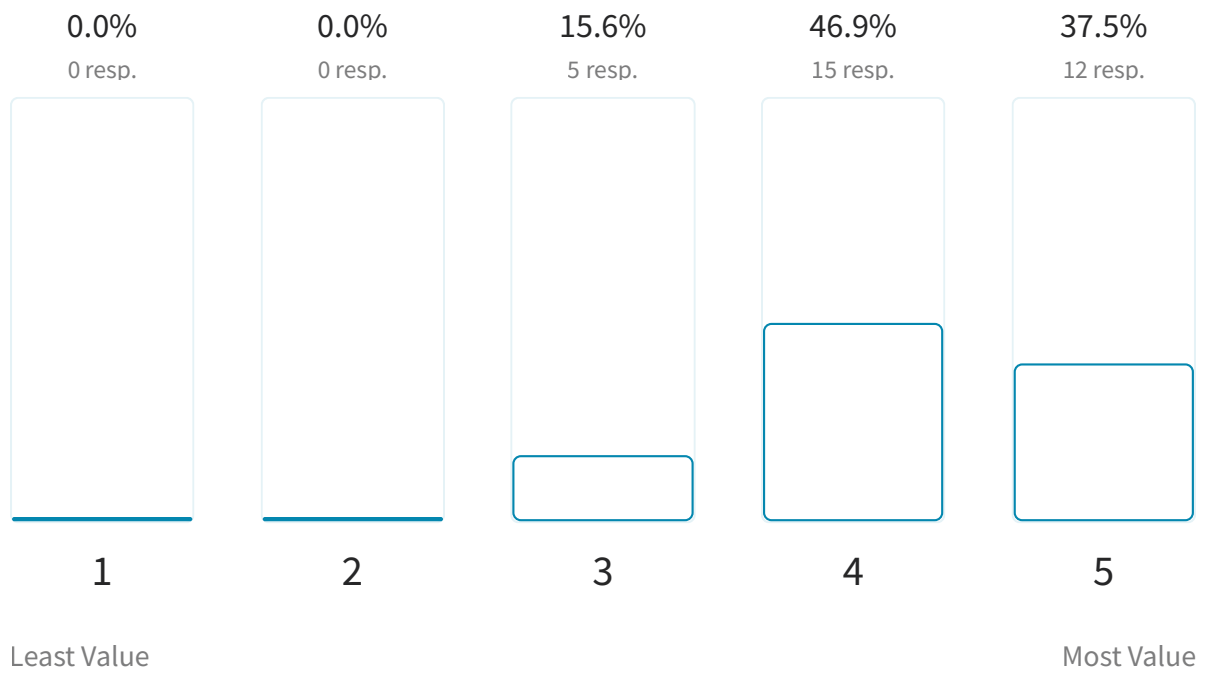
What specific value would this use case bring to your organization?

32 out of 138 answered
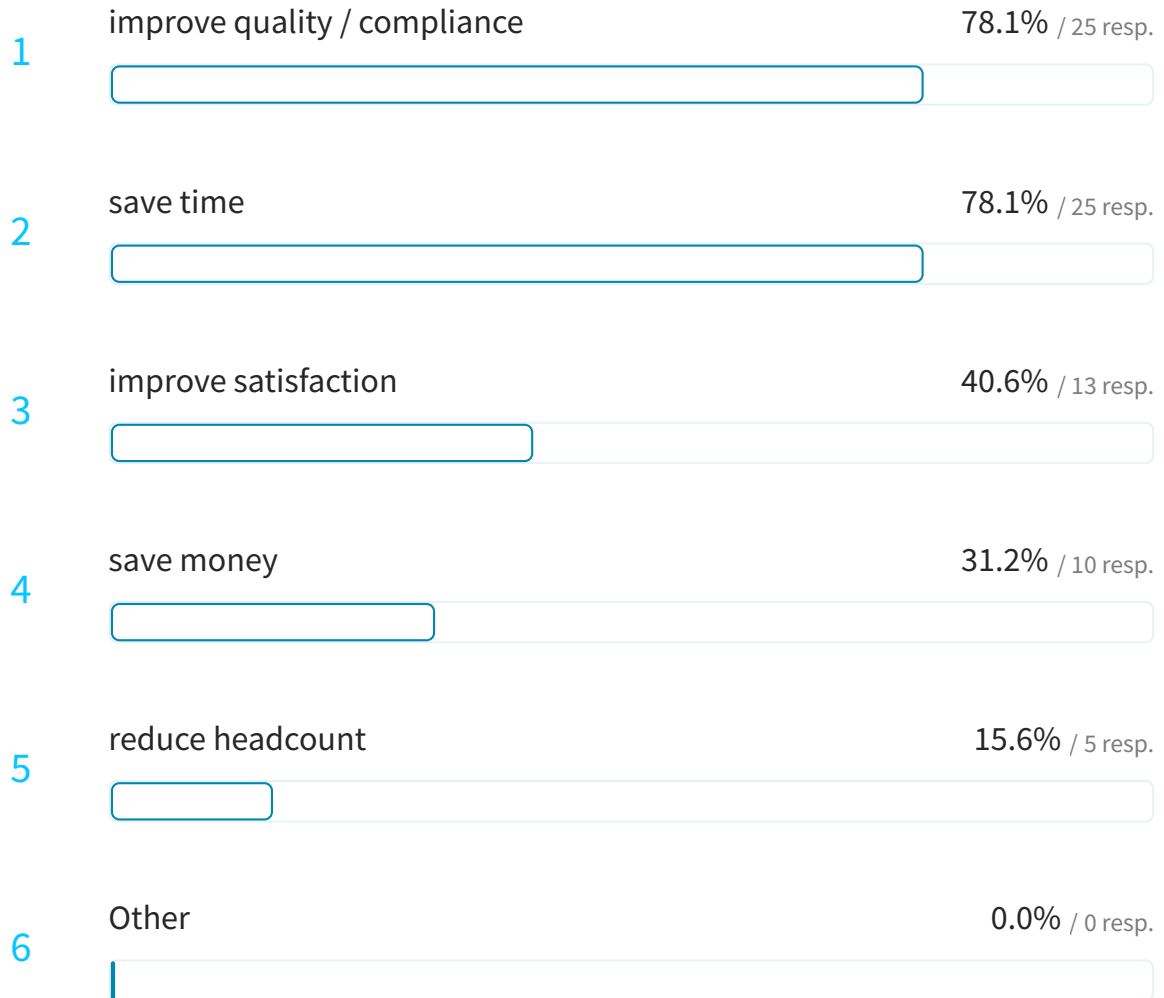
1   improve quality / compliance   78.1% / 25 resp.

2   save time   78.1% / 25 resp.

3   improve satisfaction   40.6% / 13 resp.

4   save money   31.2% / 10 resp.

5   reduce headcount   15.6% / 5 resp.

6   Other   0.0% / 0 resp.

Which part(s) of the organization would gain business value for this use case?

32 out of 138 answered

1   Clinical Operations   75.0% / 24 resp.

2   TMF Management   75.0% / 24 resp.

3   Information Technology   53.1% / 17 resp.

4   Regulatory   31.2% / 10 resp.

5   Other   3.1% / 1 resp.

Who is the decision-maker for implementing a solution for this use case?

32 out of 138 answered

1 Senior management / leadership   65.6% / 21 resp.

2 TMF Management   56.2% / 18 resp.

3 Information Technology   43.8% / 14 resp.

4 Clinical Operations   31.2% / 10 resp.

5 Regulatory   9.4% / 3 resp.

6 Other   0.0% / 0 resp.
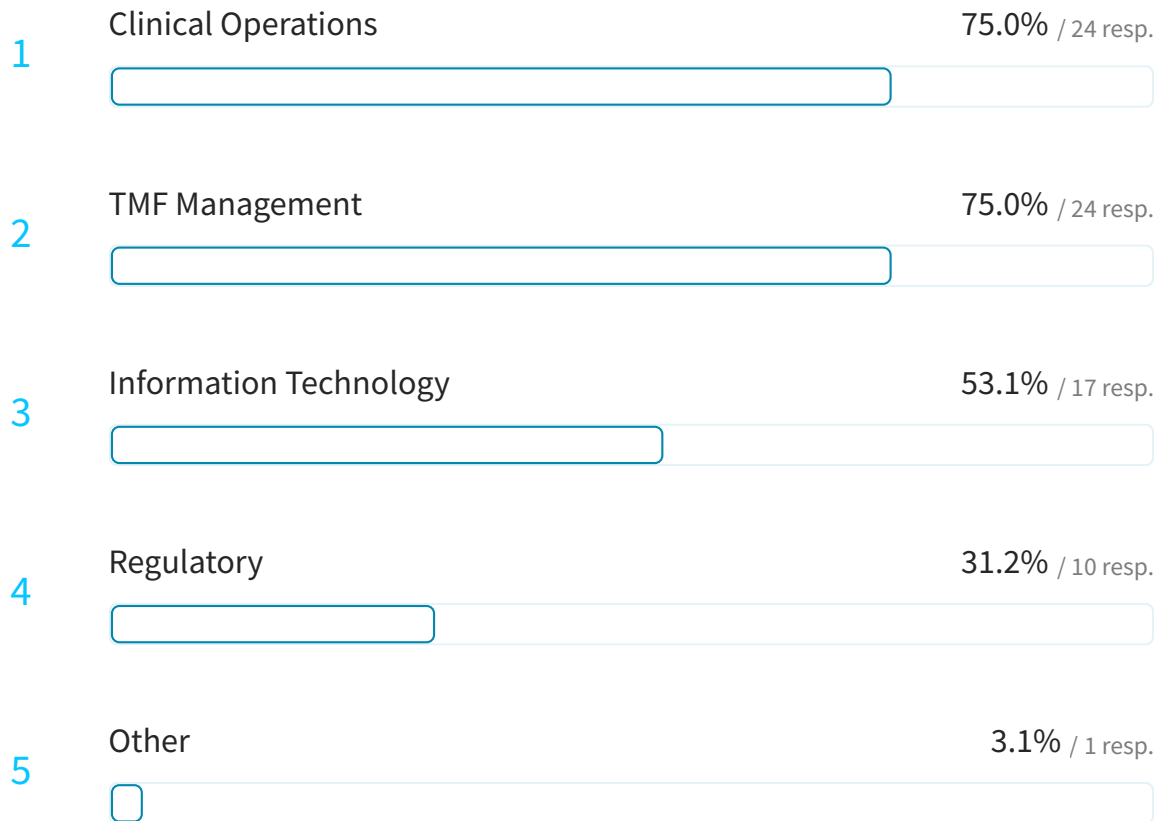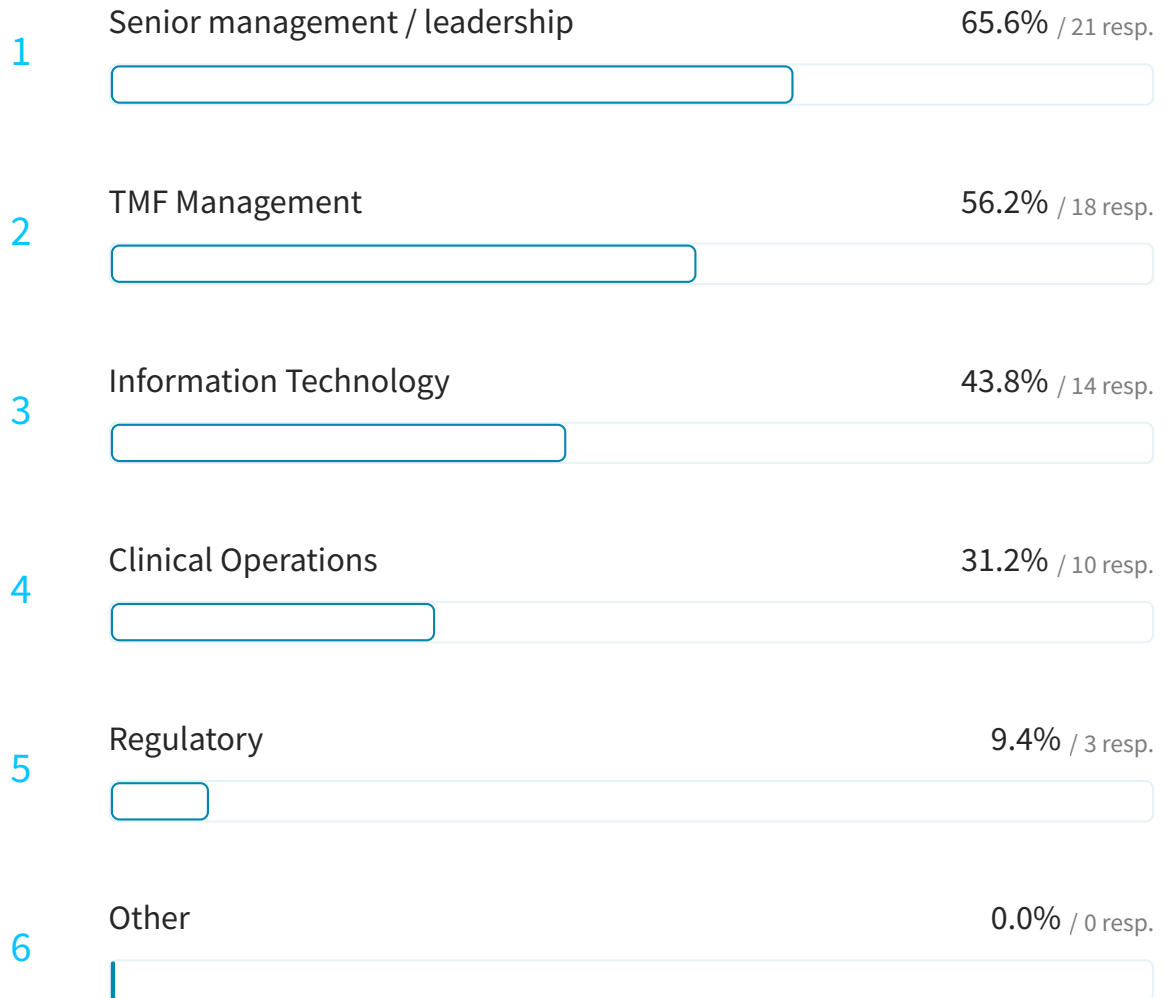
How do you currently do you currently archive TMF content and metadata?

32 out of 138 answered

1   We have developed our own archive function   40.6% / 13 resp.

2   We use our eTMF native archive function   34.4% / 11 resp.

3   We are not currently archiving TMF content   18.8% / 6 resp.

4   Other   6.2% / 2 resp.
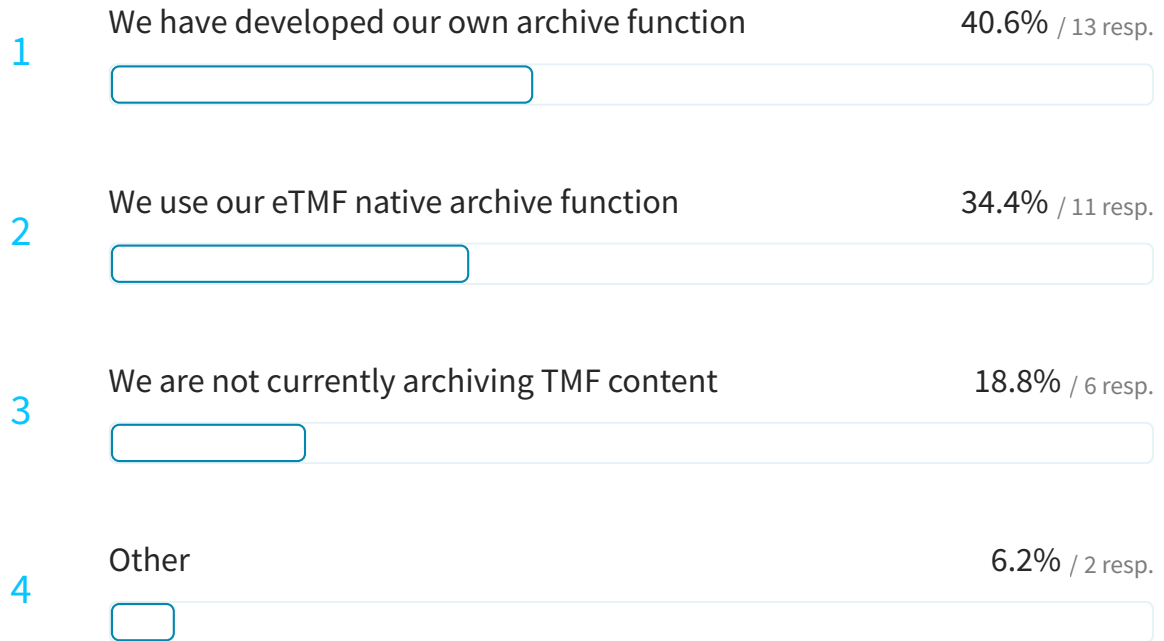
How critical would this use case be to the selection of an eTMF system or CRO?

32 out of 138 answered
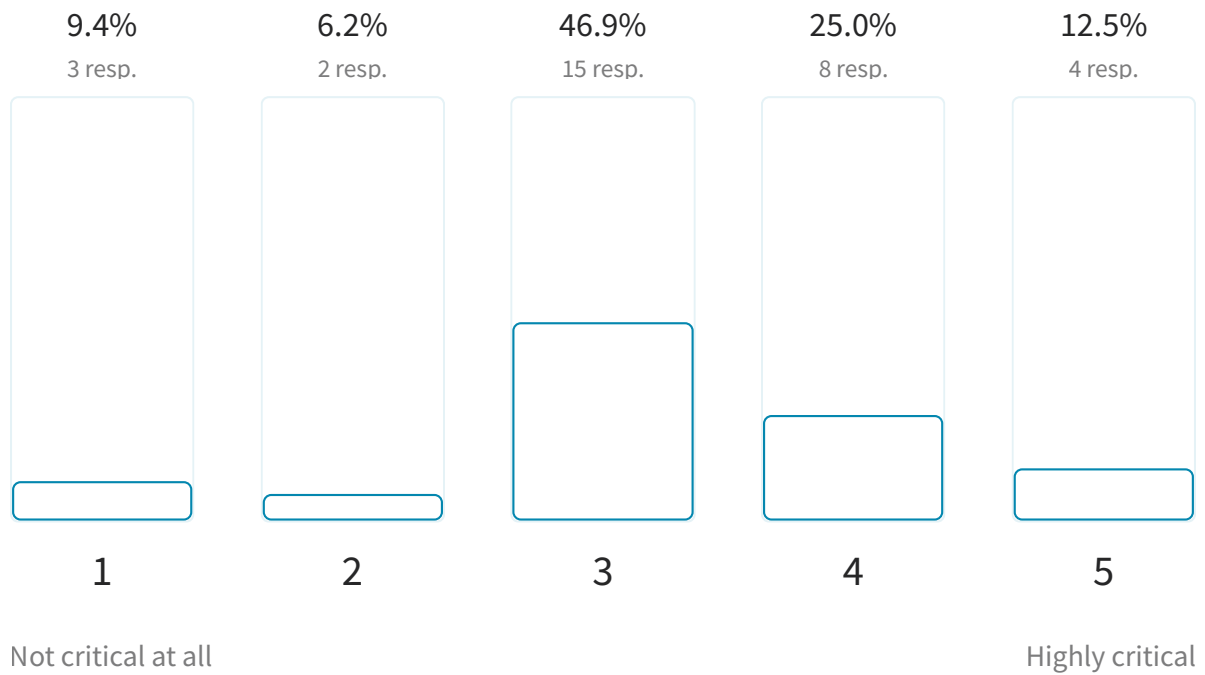
3.2 Average rating

9.4%	6.2%	46.9%	25.0%	12.5%
3 resp.	2 resp.	15 resp.	8 resp.	4 resp.
1	2	3	4	5

Not critical at all   Highly critical

What would be the overall value to your organization if you were to use the eTMF-EMS to migrate TMF content after an acquisition?

23 out of 138 answered

4.1 Average rating

4.3%	0.0%	4.3%	60.9%	30.4%
1 resp.	0 resp.	1 resp.	14 resp.	7 resp.
1	2	3	4	5

Least Value   Most Value
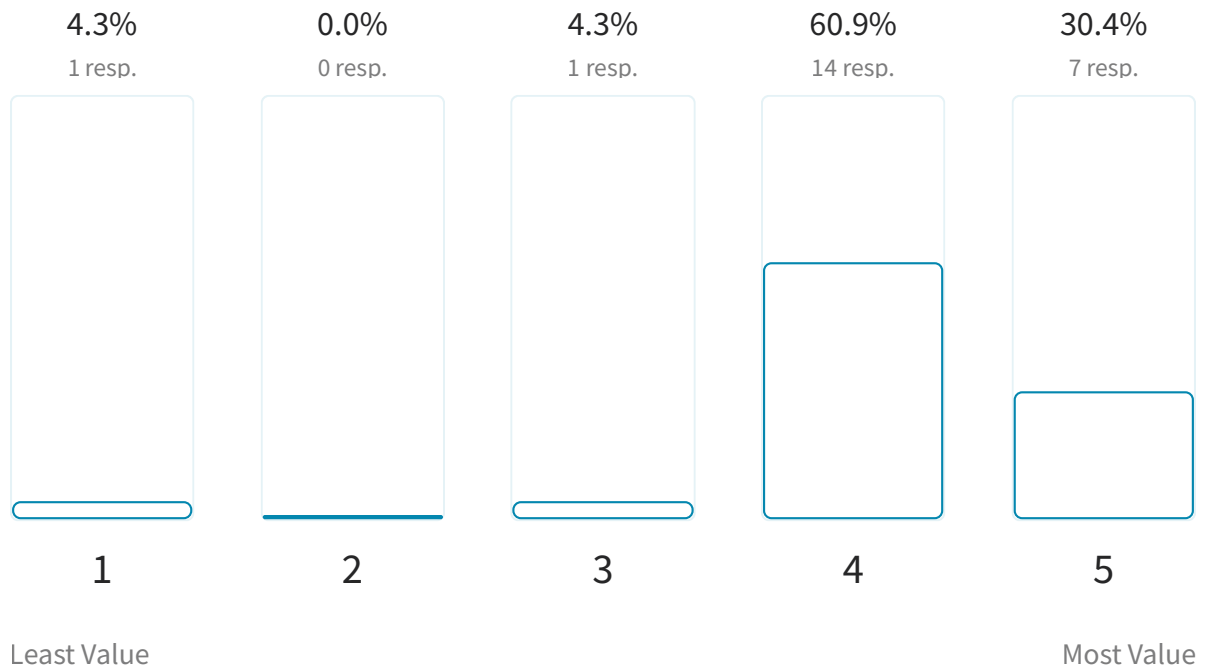
What specific value would this use case bring to your organization?

23 out of 138 answered
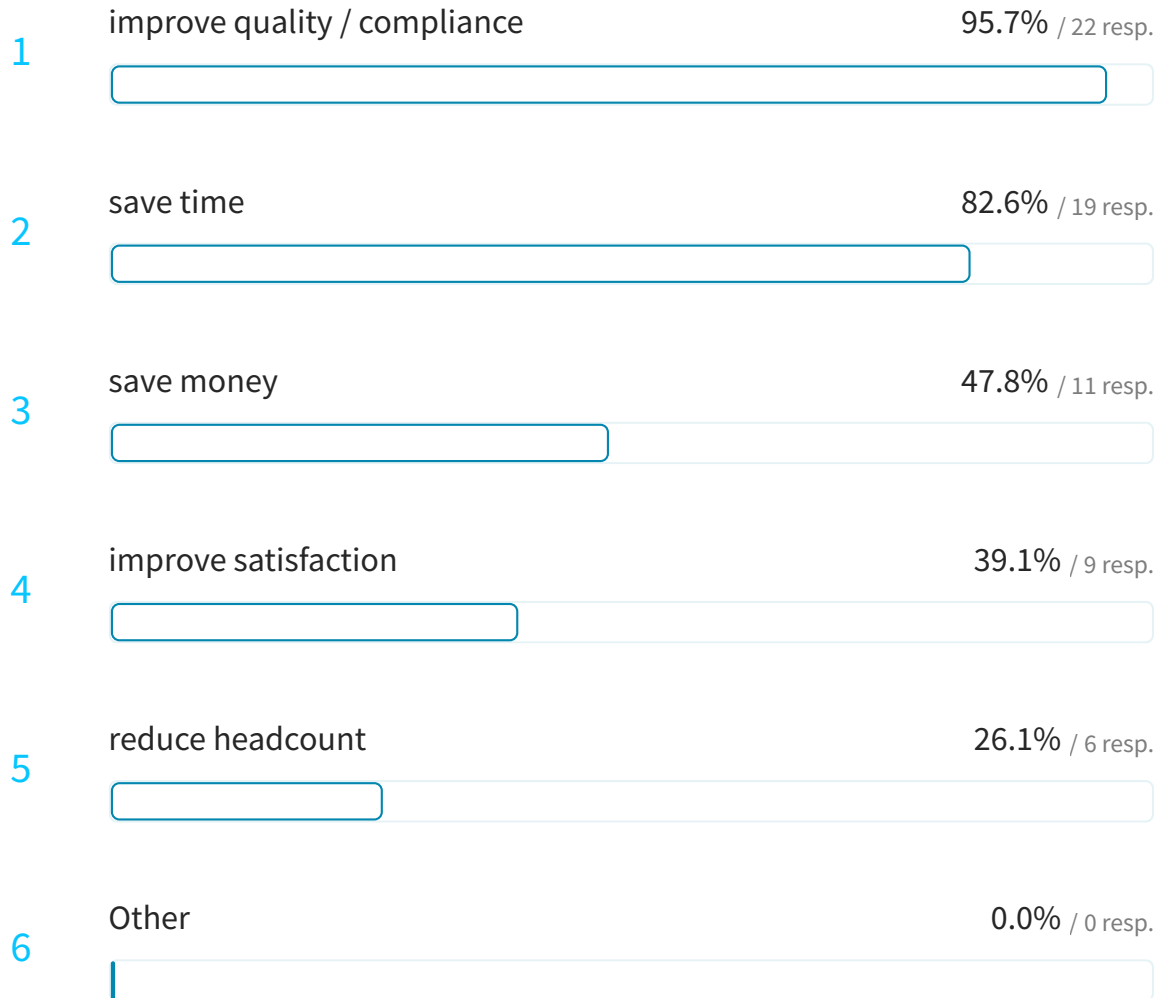
1   improve quality / compliance   95.7% / 22 resp.

2   save time   82.6% / 19 resp.

3   save money   47.8% / 11 resp.

4   improve satisfaction   39.1% / 9 resp.

5   reduce headcount   26.1% / 6 resp.

6   Other   0.0% / 0 resp.

Which part(s) of the organization would gain business value for this use case?

23 out of 138 answered

1   TMF Management   87.0% / 20 resp.

2   Clinical Operations   78.3% / 18 resp.

3   Regulatory   47.8% / 11 resp.

4   Information Technology   39.1% / 9 resp.

5   Other   0.0% / 0 resp.

Who is the decision-maker for implementing a solution for this use case?

23 out of 138 answered

1   Senior management / leadership   78.3% / 18 resp.

2   TMF Management   56.5% / 13 resp.

3   Information Technology   52.2% / 12 resp.

4   Clinical Operations   21.7% / 5 resp.

5   Regulatory   13.0% / 3 resp.

6   Other   0.0% / 0 resp.
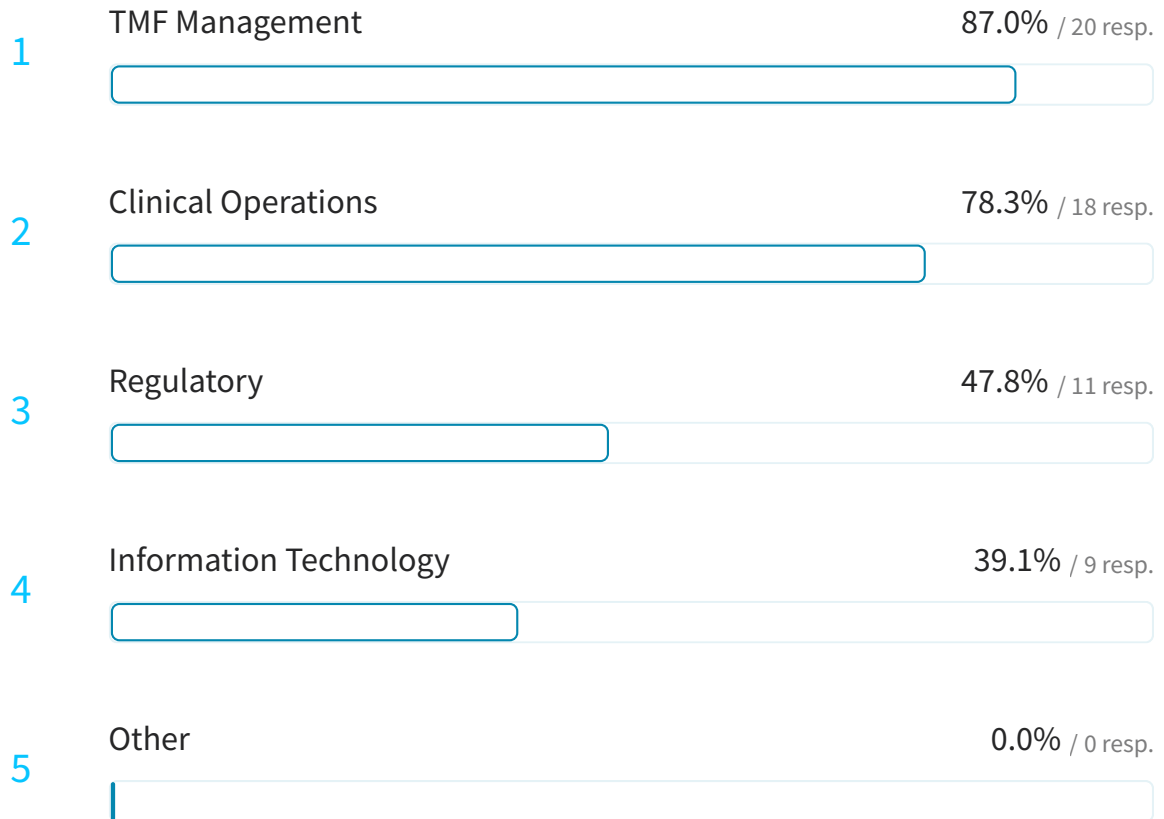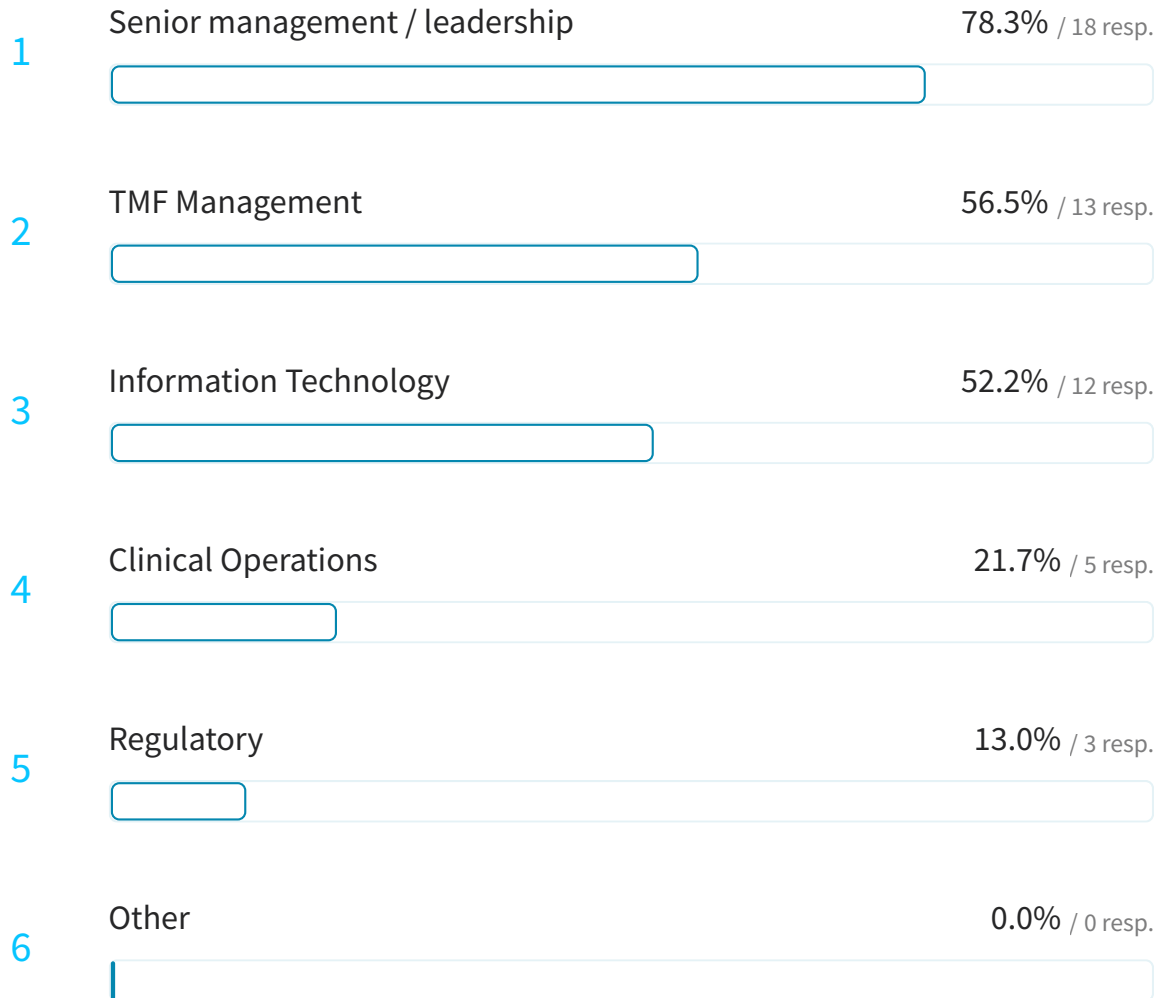
How have you migrated TMF content in the past after an acquisition?

23 out of 138 answered

1   We archived the content and didn't migrate it   30.4% / 7 resp.

2   We mapped the content from the source system and then
     loaded it into our system   26.1% / 6 resp.

3   We manually uploaded to our eTMF document by
     document   17.4% / 4 resp.

4   Don't know as we have not done any acquisitons   4.3% / 1 resp.

5   We had an integration with the source and destination
     system which allowed us to transfer the content   4.3% / 1 resp.

6   Other   17.4% / 4 resp.
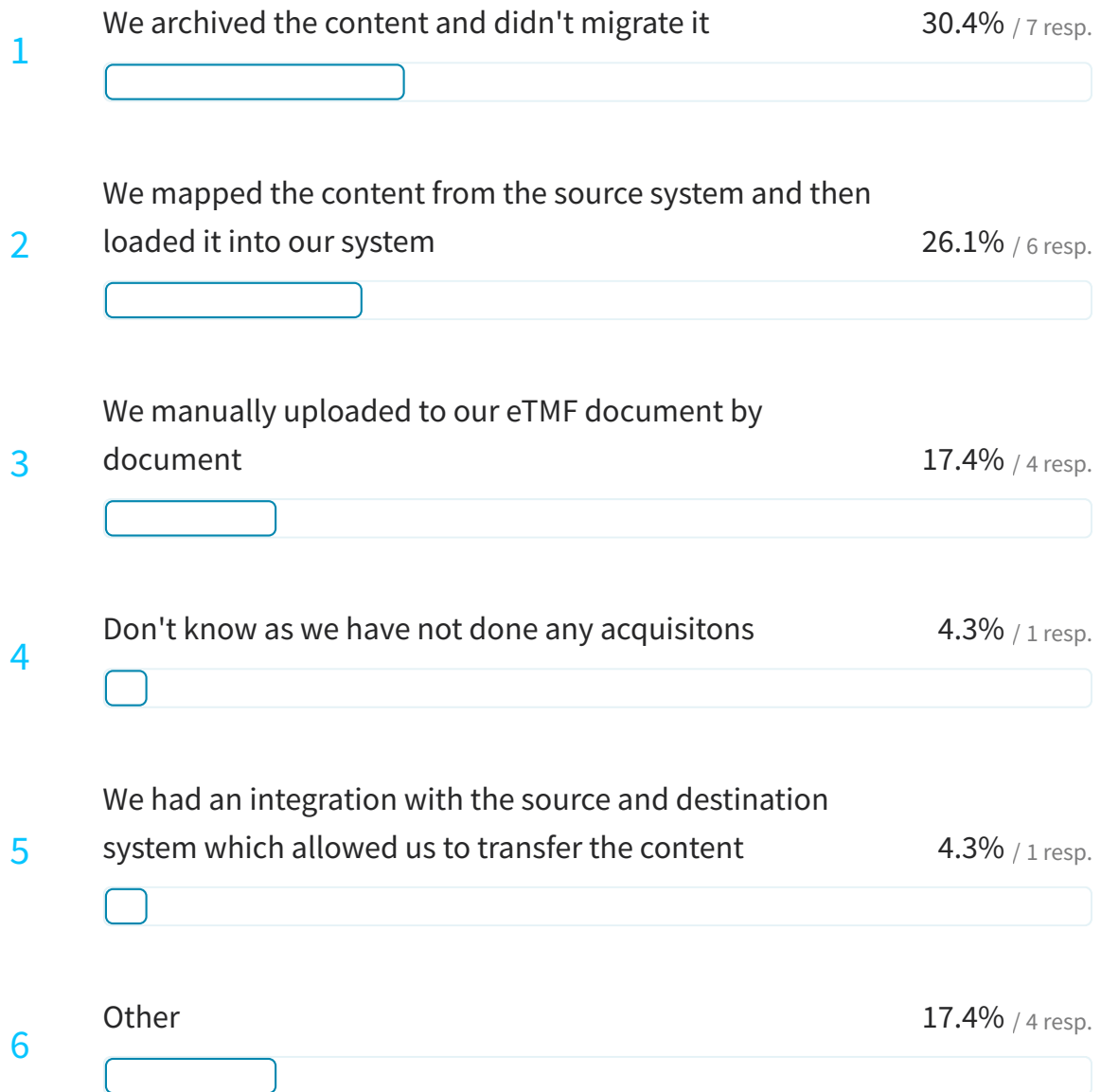
How critical would this use case be to the selection of an eTMF system or CRO?

23 out of 138 answered

3.4 Average rating

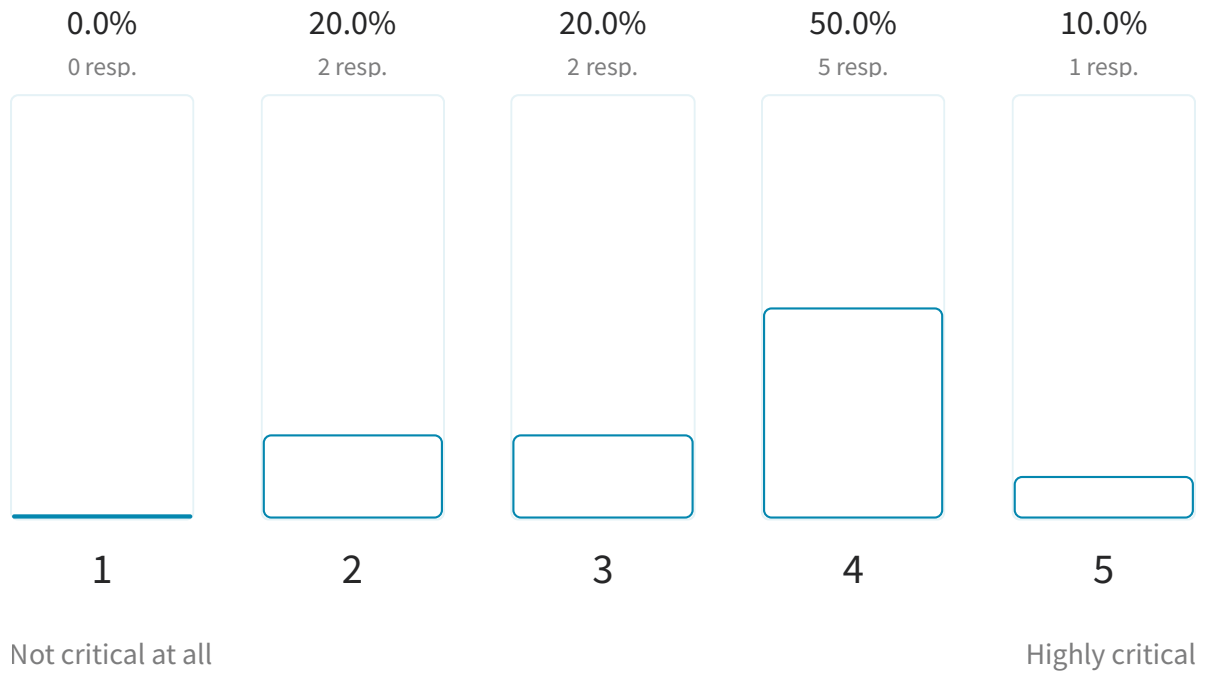| 17.4%	4.3%	13.0%	52.2%	13.0%
4 resp.	1 resp.	3 resp.	12 resp.	3 resp.
1	2	3	4	5

Not critical at all   Highly critical
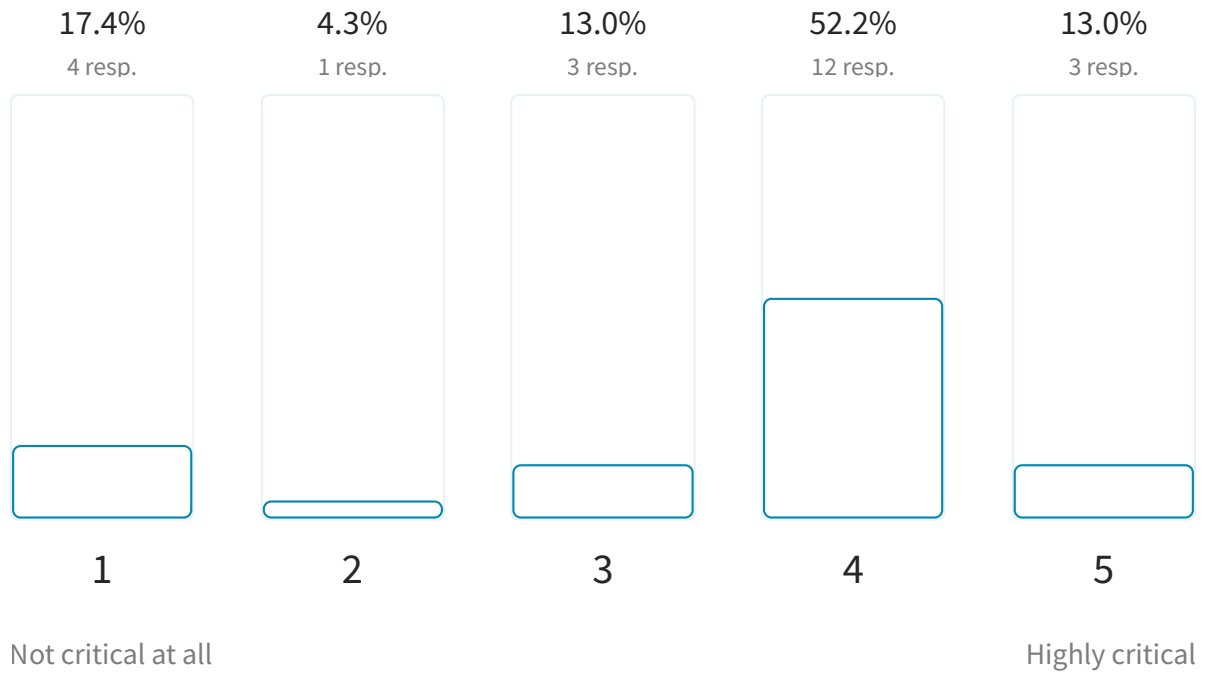
What would be the overall value to your organization if you were to transport records after upgrading/changing an eTMF system?

10 out of 138 answered

4.2 Average rating

0.0%	10.0%	0.0%	50.0%	40.0%
0 resp.	1 resp.	0 resp.	5 resp.	4 resp.
1	2	3	4	5

Least Value   Most Value
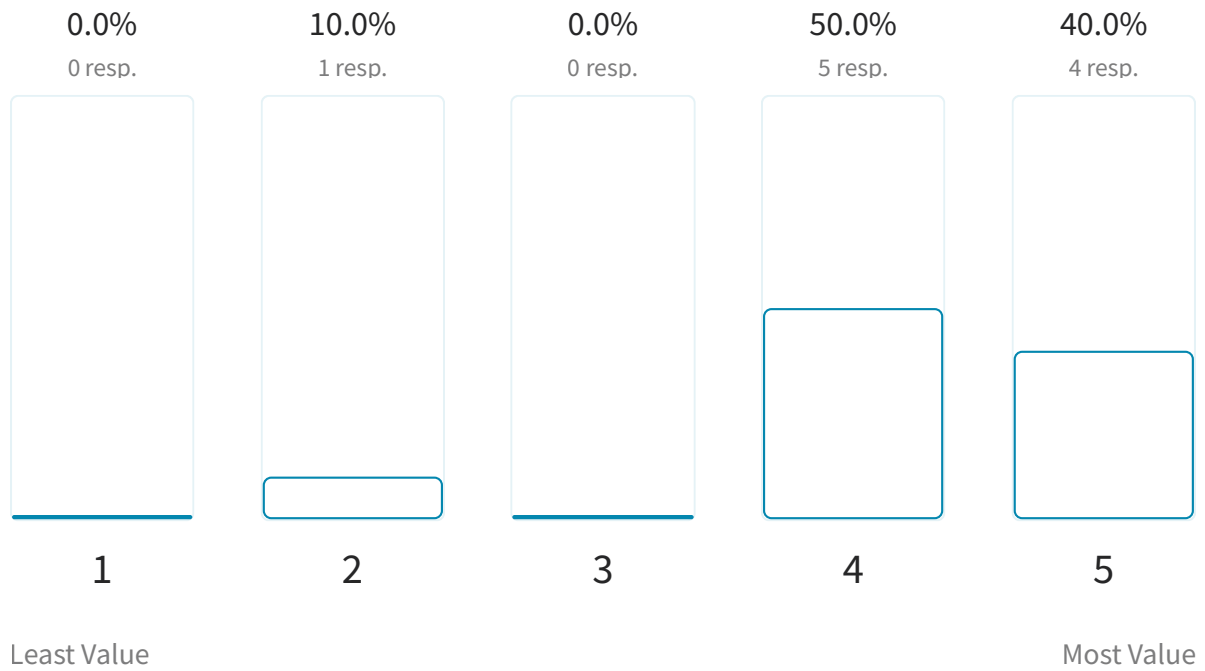
What specific value would this use case bring to your organization?

10 out of 138 answered
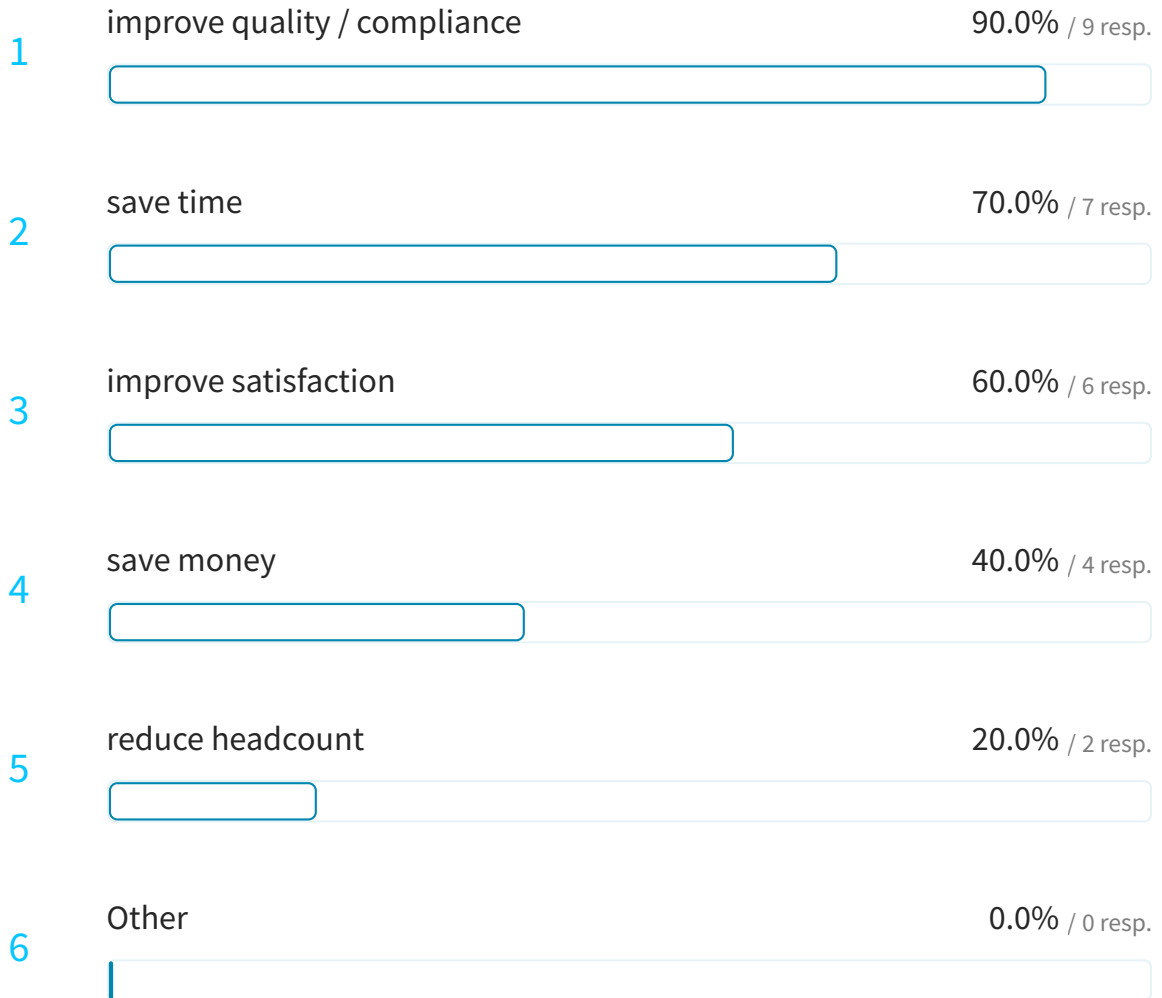
1   improve quality / compliance   90.0% / 9 resp.

2   save time   70.0% / 7 resp.

3   improve satisfaction   60.0% / 6 resp.

4   save money   40.0% / 4 resp.

5   reduce headcount   20.0% / 2 resp.

6   Other   0.0% / 0 resp.

Which part(s) of the organization would gain business value for this use case?

10 out of 138 answered

1 Clinical Operations

100.0% / 10 resp.

2 TMF Management

80.0% / 8 resp.

3 Information Technology

20.0% / 2 resp.

4 Regulatory

20.0% / 2 resp.

5 Other

0.0% / 0 resp.

Who is the decision-maker for implementing a solution for this use case?

10 out of 138 answered

1   Senior management / leadership   80.0% / 8 resp.

2   Clinical Operations   50.0% / 5 resp.

3   Information Technology   30.0% / 3 resp.

4   TMF Management   30.0% / 3 resp.

5   Regulatory   0.0% / 0 resp.

6   Other   0.0% / 0 resp.
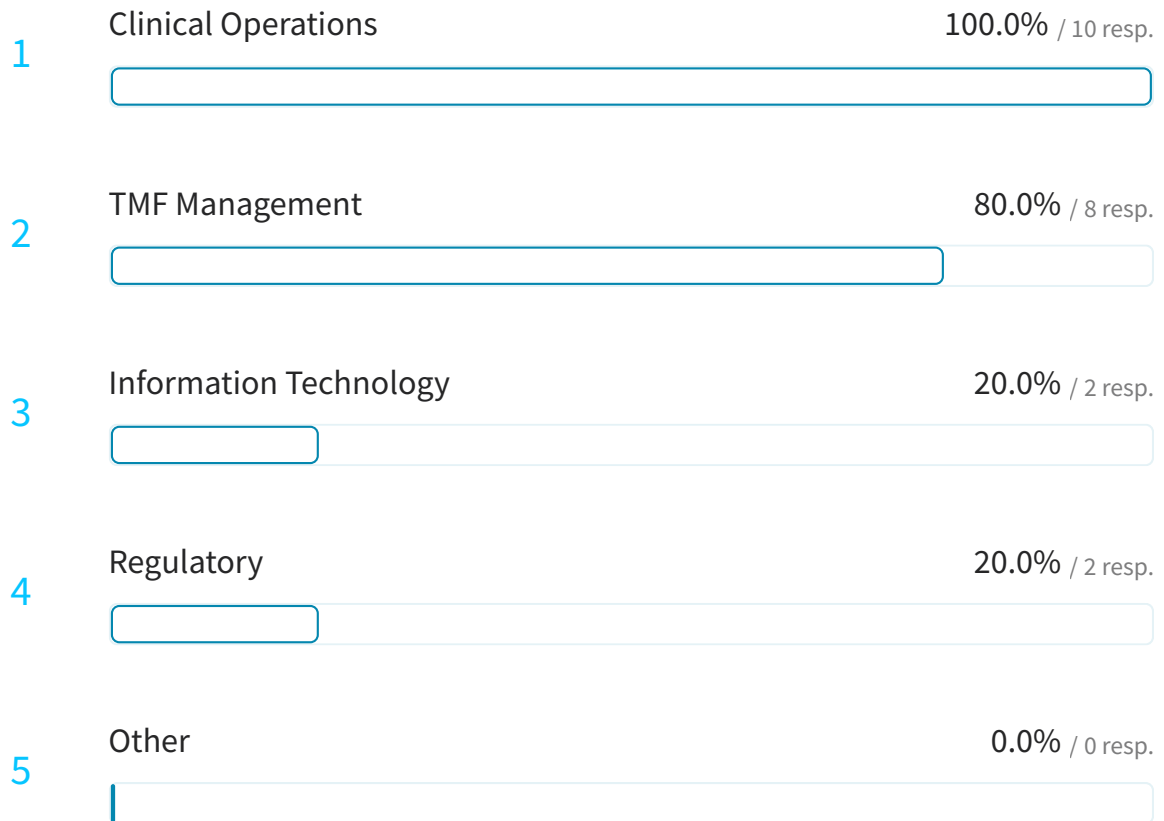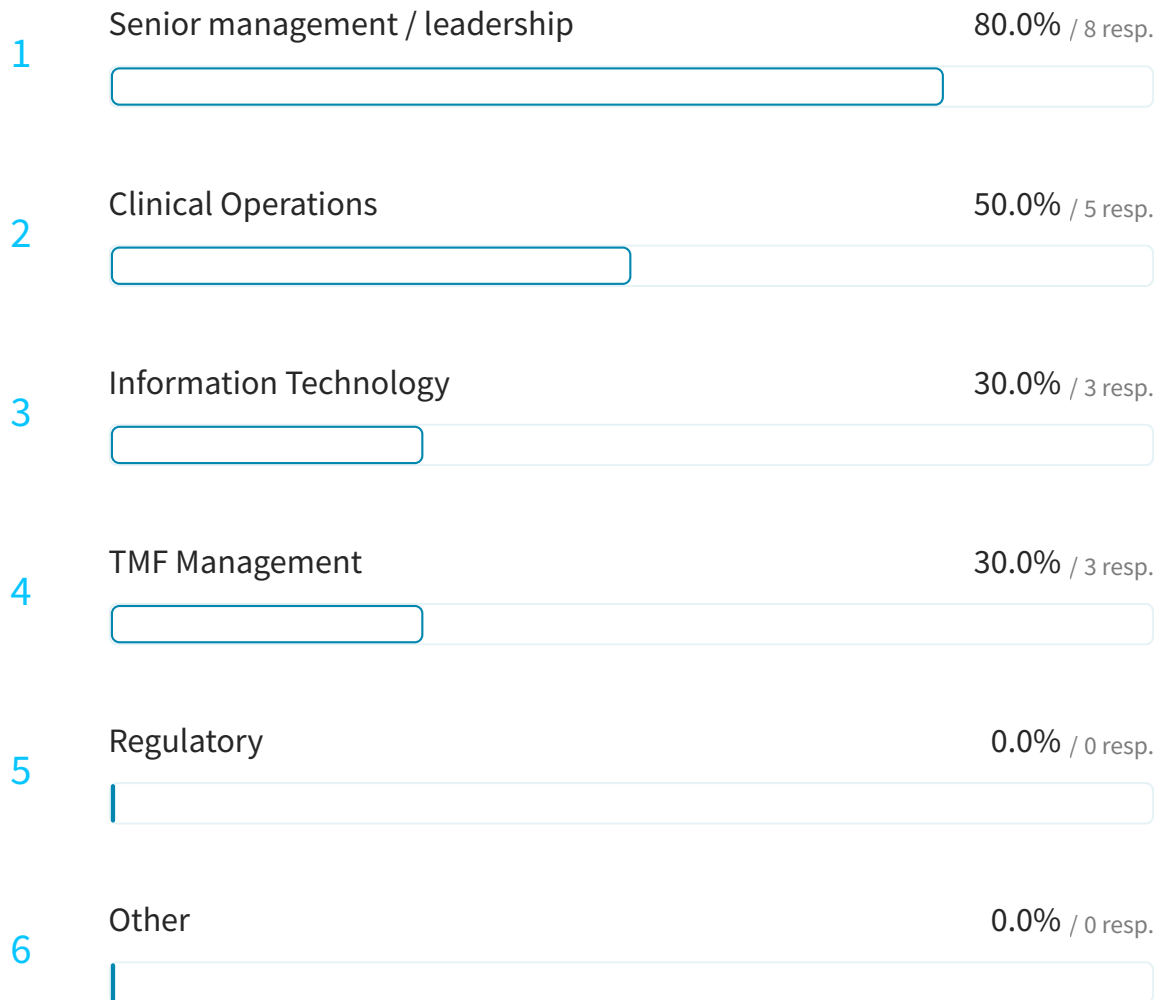
If you have already upgraded/changed eTMF system, how did you migrate the content?

10 out of 138 answered

1   We have not upgraded or changed our eTMF system   40.0% / 4 resp.

2   It was migrated by our eTMF vendor for us   20.0% / 2 resp.

3   We had to manually migrate content   20.0% / 2 resp.

4   We were able to map the old system to the new and
    automatically migrate content   20.0% / 2 resp.

5   Other   0.0% / 0 resp.
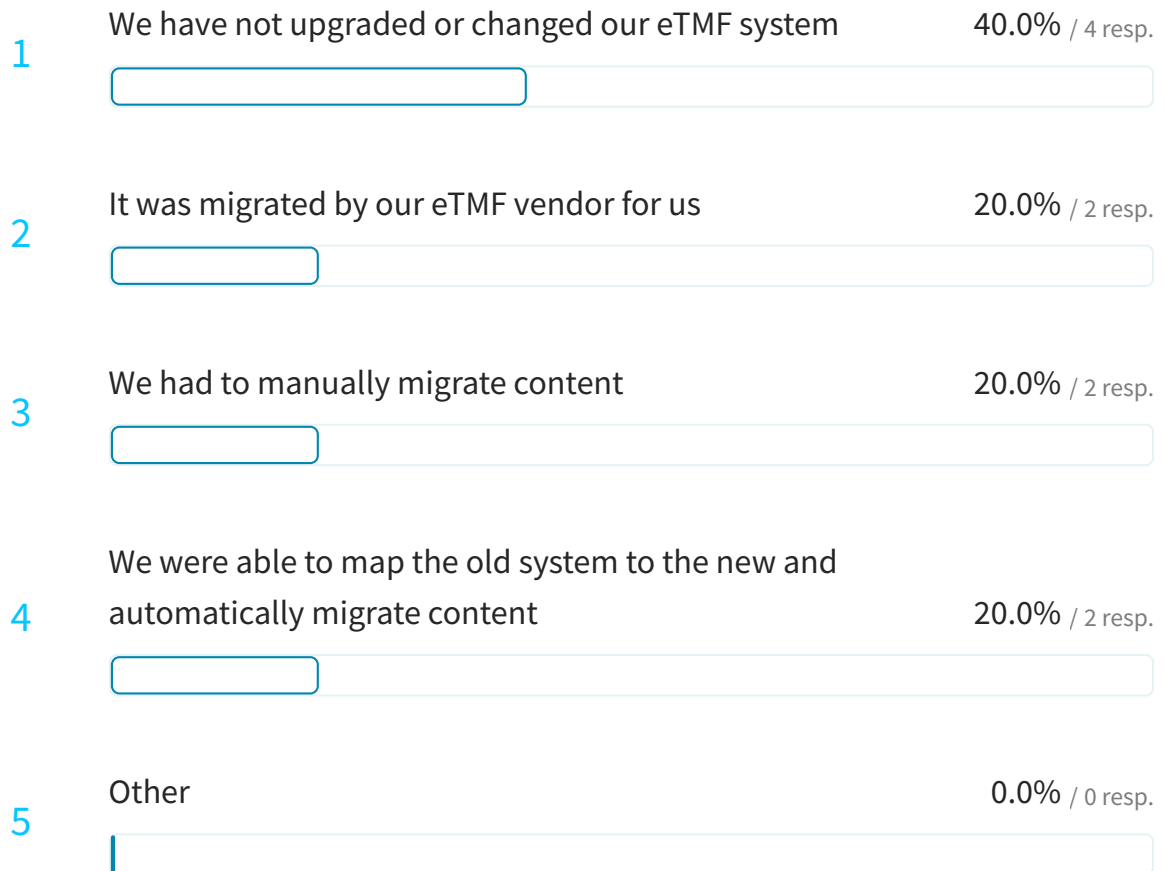
How critical would this use case be to the selection of an eTMF system or CRO?

10 out of 138 answered

3.5 Average rating

0.0%	20.0%	20.0%	50.0%	10.0%
0 resp.	2 resp.	2 resp.	5 resp.	1 resp.

| 1 | 2 | 3 | 4 | 5 |

Not critical at all   Highly critical

What would be the overall value to your organization if you were to use the eTMF-EMS to transfer Sponsor TMF content to and from a Study Site?

18 out of 138 answered

4.2 Average rating

0.0%	0.0%	11.1%	61.1%	27.8%
0 resp.	0 resp.	2 resp.	11 resp.	5 resp.
1	2	3	4	5

Least Value   Most Value
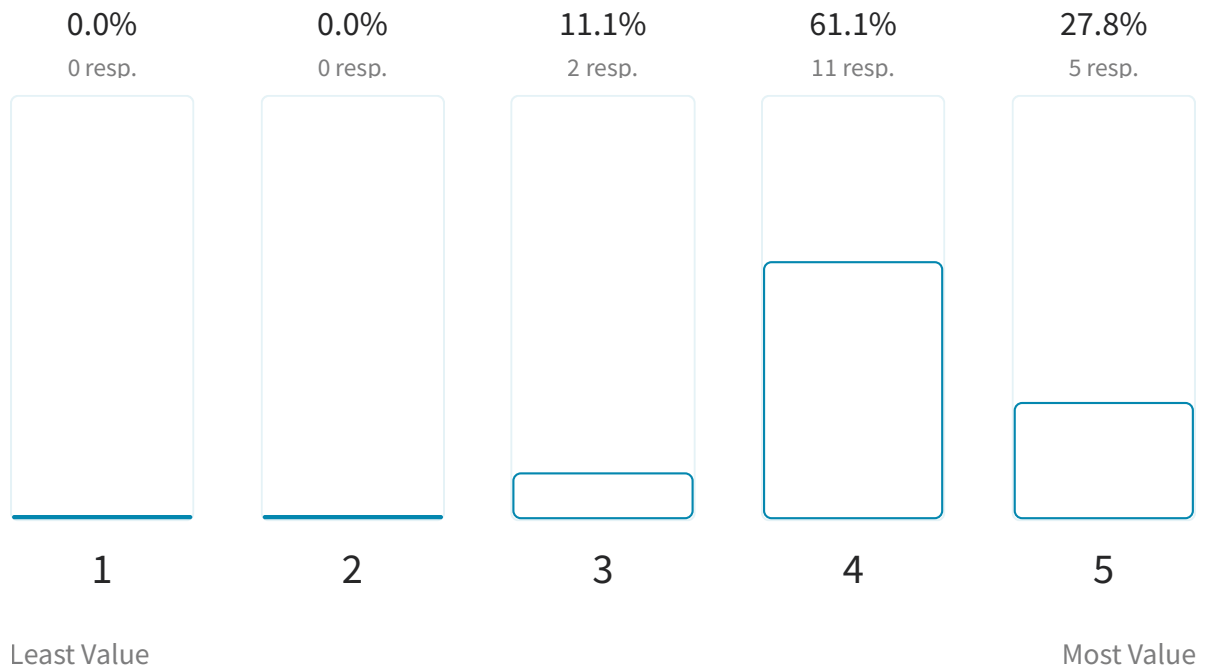
What specific value would this use case bring to your organization?

18 out of 138 answered
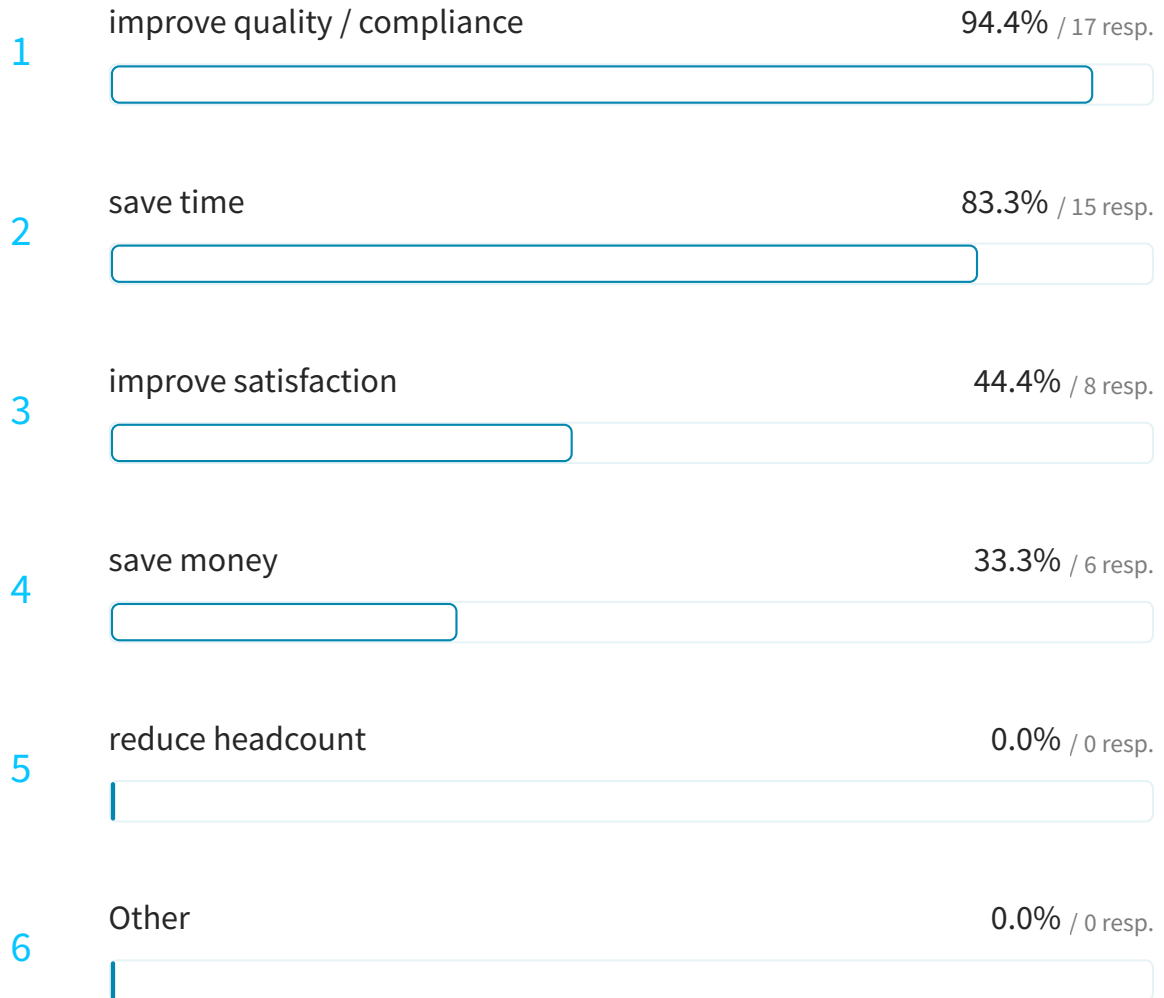
1 improve quality / compliance

94.4% / 17 resp.

2 save time

83.3% / 15 resp.

3 improve satisfaction

44.4% / 8 resp.

4 save money

33.3% / 6 resp.

5 reduce headcount

0.0% / 0 resp.

6 Other

0.0% / 0 resp.

Which part(s) of the organization would gain business value for this use case?

18 out of 138 answered

1   Clinical Operations   94.4% / 17 resp.

2   TMF Management   77.8% / 14 resp.

3   Regulatory   38.9% / 7 resp.

4   Information Technology   5.6% / 1 resp.

5   Other   0.0% / 0 resp.

Who is the decision-maker for implementing a solution for this use case?

18 out of 138 answered

1   Senior management / leadership   72.2% / 13 resp.

2   Clinical Operations   50.0% / 9 resp.

3   TMF Management   33.3% / 6 resp.

4   Information Technology   22.2% / 4 resp.

5   Regulatory   5.6% / 1 resp.

6   Other   0.0% / 0 resp.
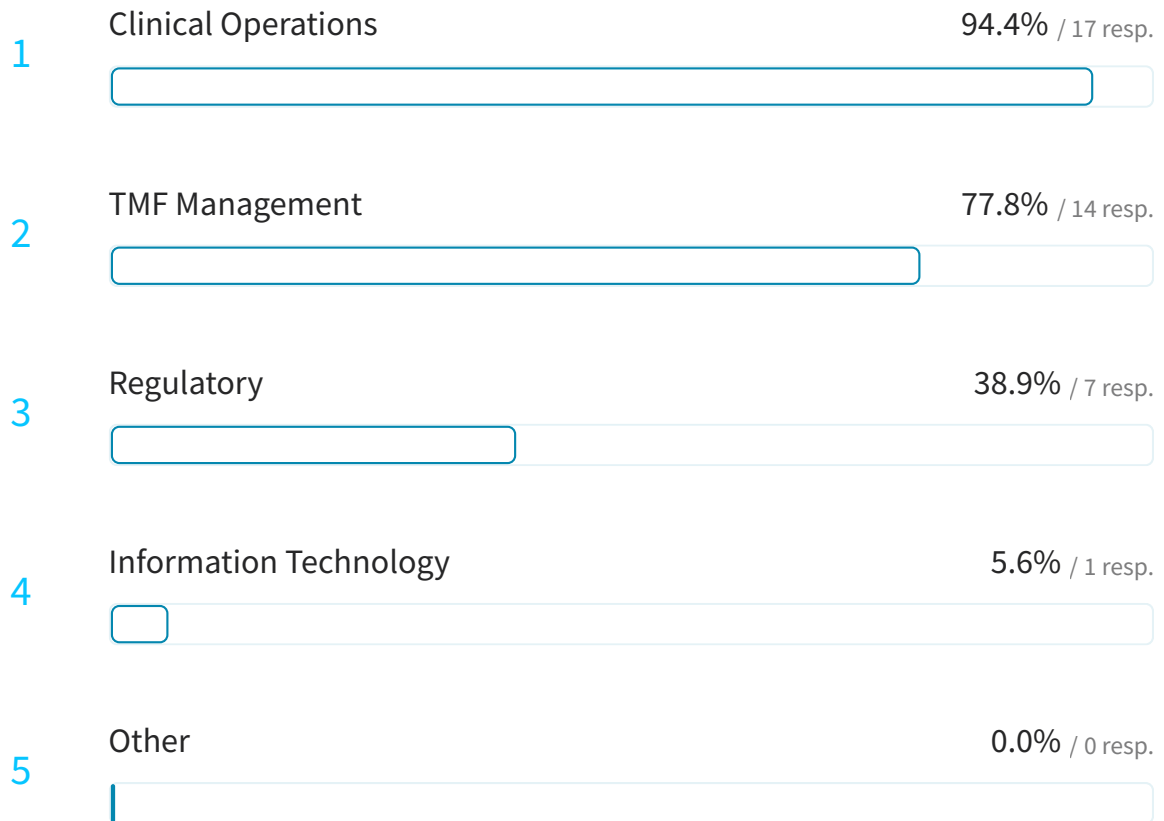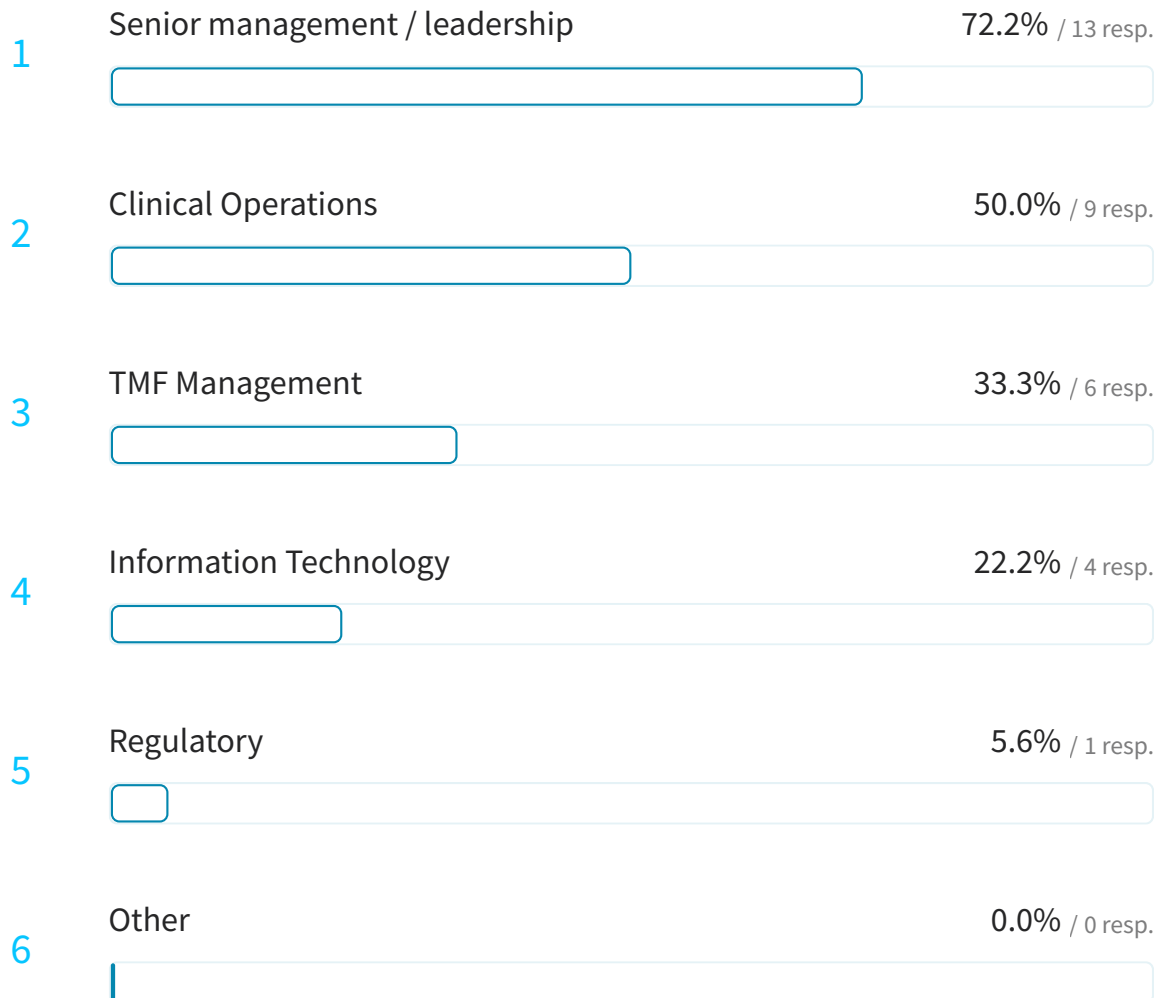
How do you currently transfer sponsor TMF content to and from study sites?

18 out of 138 answered

1 We send and receive it via email   55.6% / 10 resp.

2 We use the sites/sponsors own system to provide and
       retrieve content   22.2% / 4 resp.

3 We have an integrated site portal in our eTMF which allows
       us to send and receive content   11.1% / 2 resp.

4 We have site/sponsor send paper copies via messenger
       service   5.6% / 1 resp.

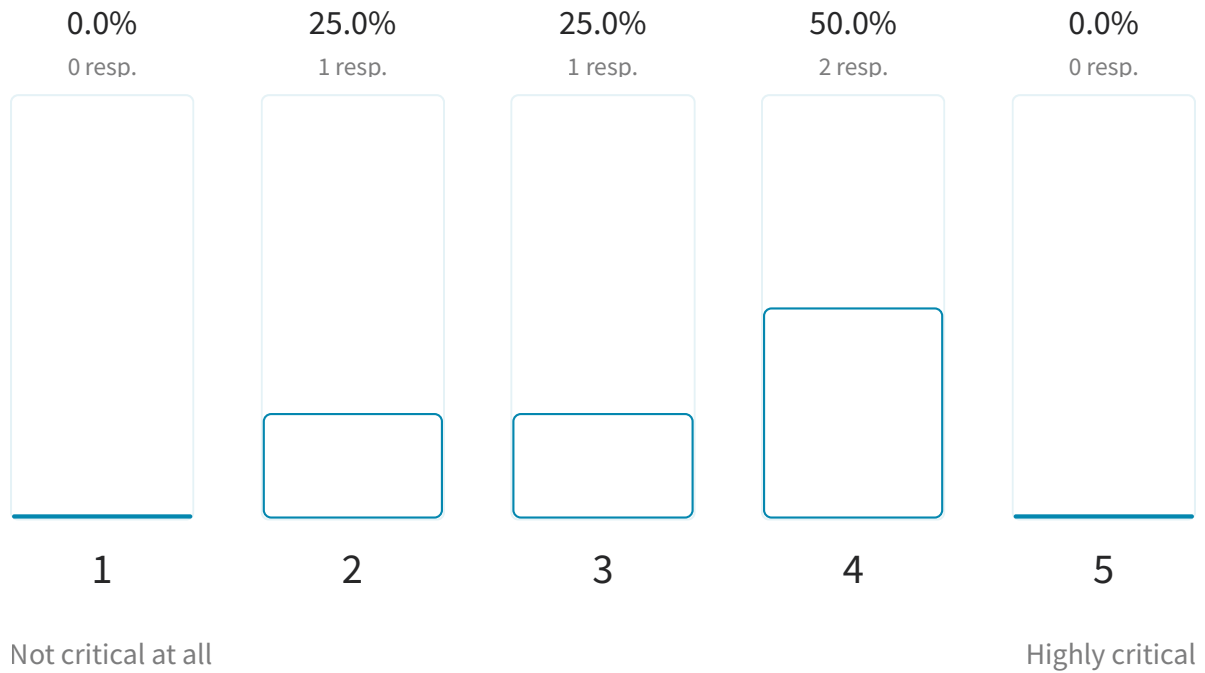**5** Other   5.6% / 1 resp.
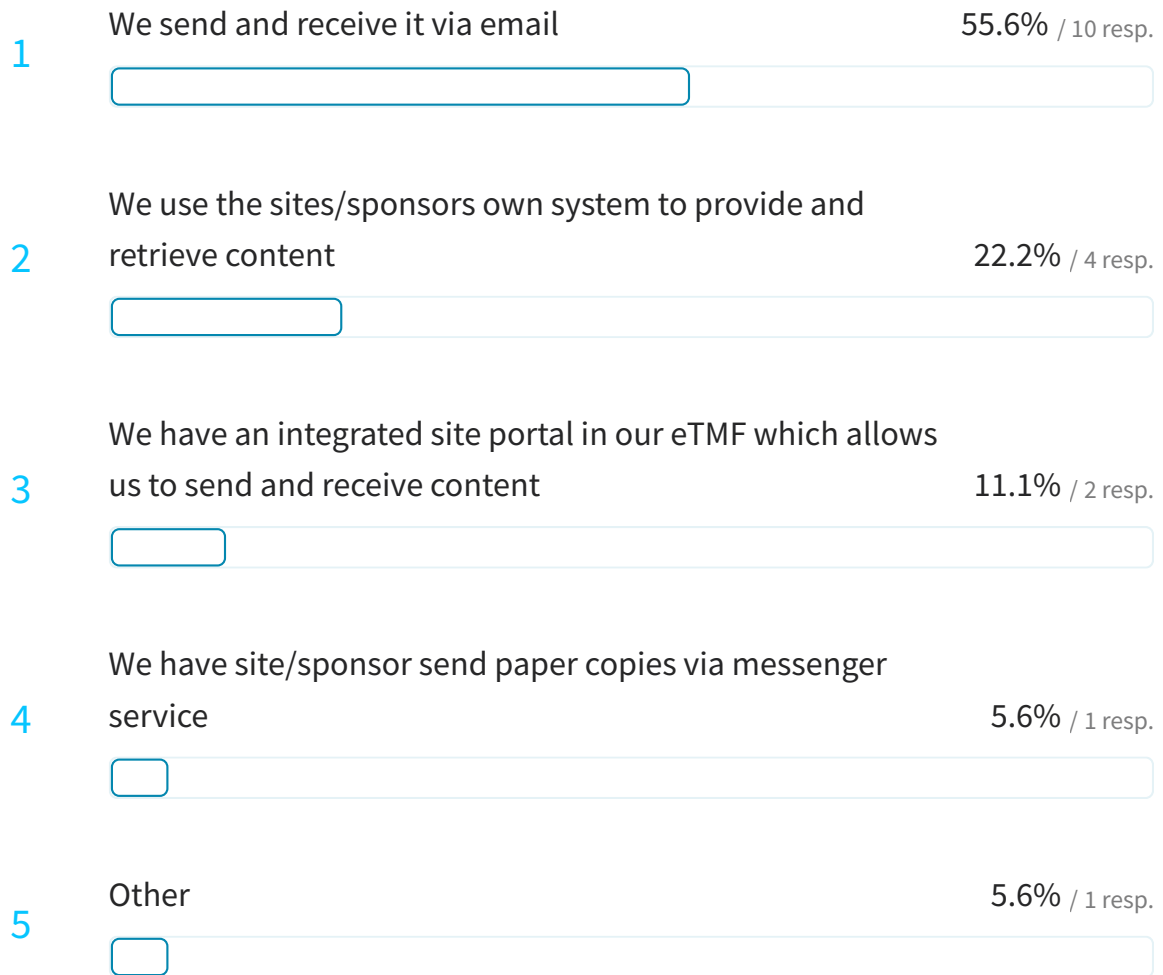
How critical would this use case be to the selection of an eTMF system or CRO?

18 out of 138 answered
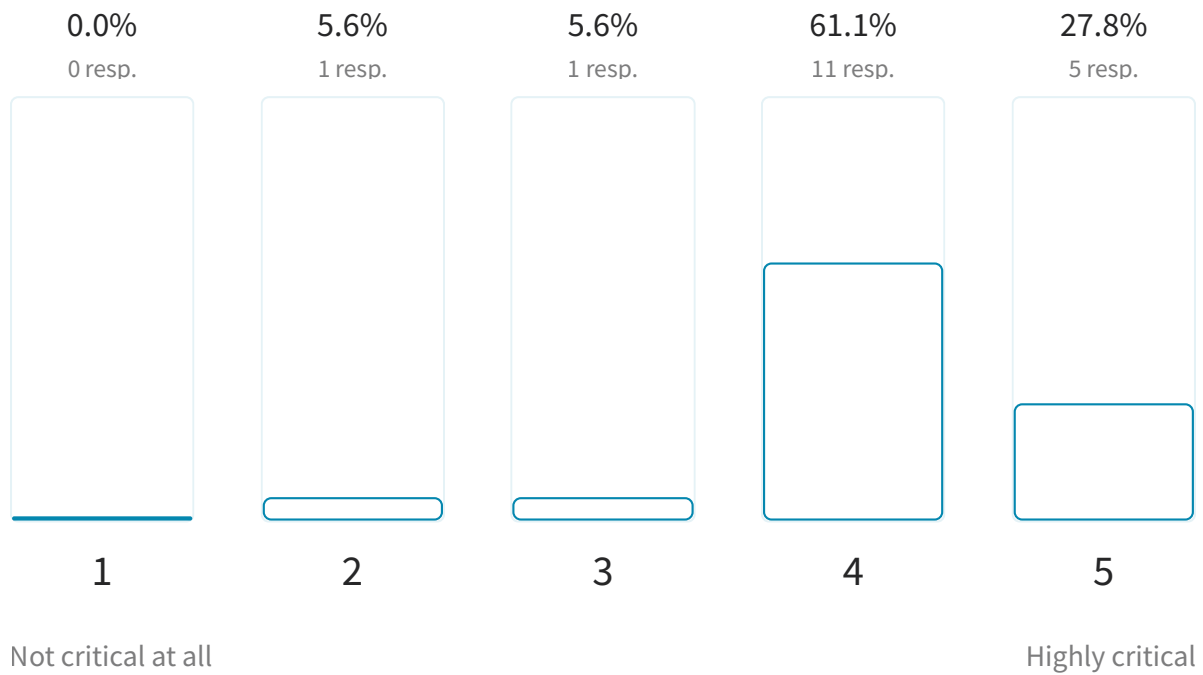
4.1 Average rating

0.0%	5.6%	5.6%	61.1%	27.8%
0 resp.	1 resp.	1 resp.	11 resp.	5 resp.
1	2	3	4	5

Not critical at all   Highly critical

What would be the overall value to your organization if you were to use the eTMF-EMS to transfer interim TMF content?

4 out of 138 answered

3.5 Average rating

0.0%	0.0%	50.0%	50.0%	0.0%
0 resp.	0 resp.	2 resp.	2 resp.	0 resp.

1	2	3	4	5

Least Value   Most Value
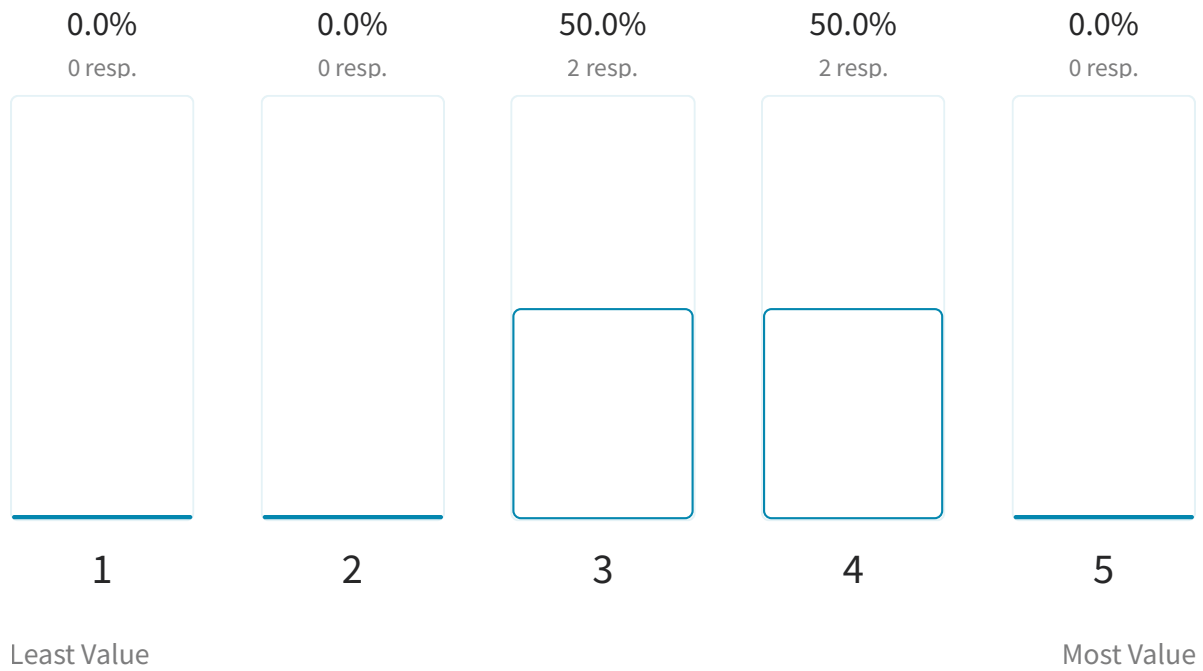
What specific value would this use case bring to your organization?

4 out of 138 answered
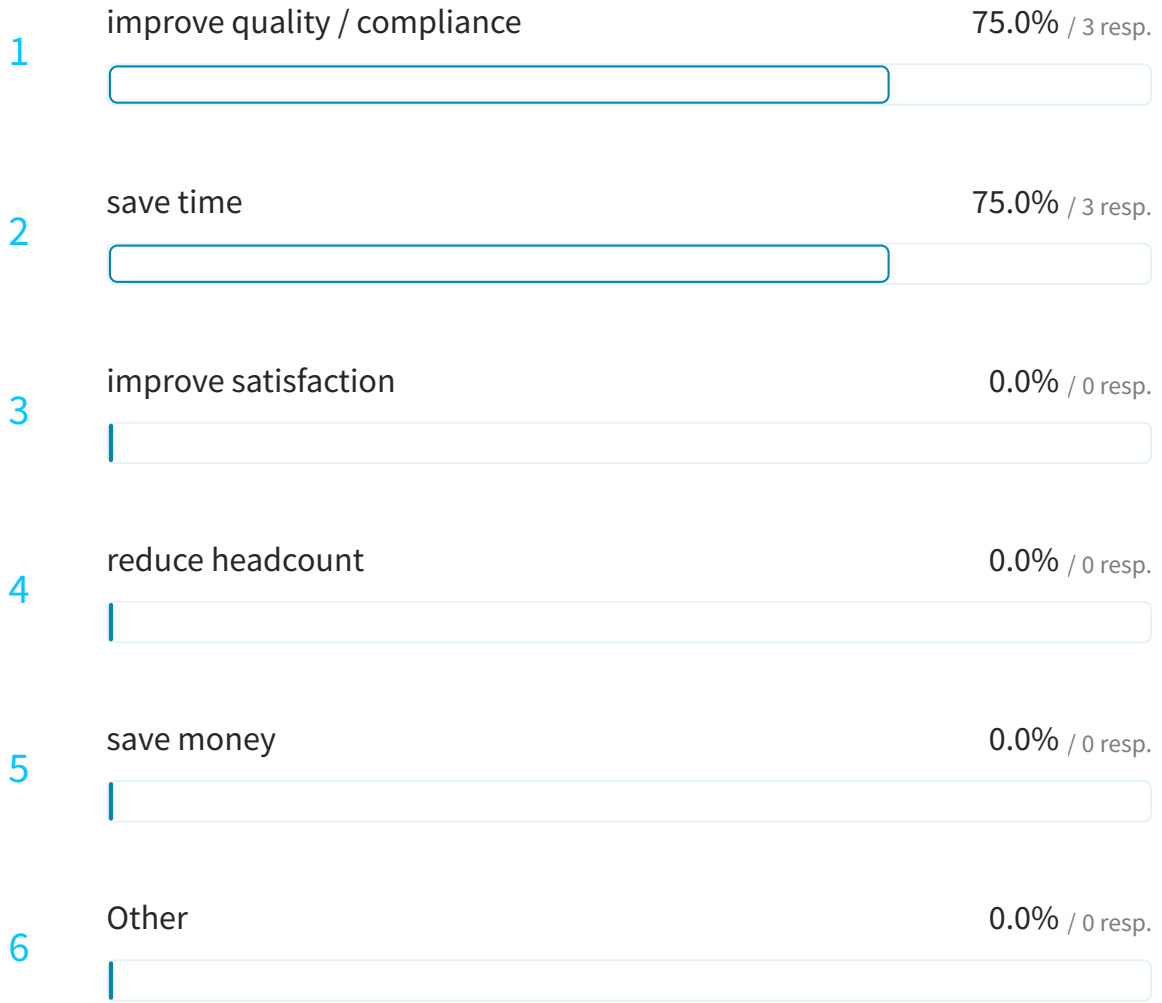
1	improve quality / compliance	75.0% / 3 resp.
2	save time	75.0% / 3 resp.
3	improve satisfaction	0.0% / 0 resp.
4	reduce headcount	0.0% / 0 resp.
5	save money	0.0% / 0 resp.
6	Other	0.0% / 0 resp.

Which part(s) of the organization would gain business value for this use case?

4 out of 138 answered

1   Clinical Operations   100.0% / 4 resp.

2   TMF Management   75.0% / 3 resp.

3   Information Technology   0.0% / 0 resp.

4   Regulatory   0.0% / 0 resp.

5   Other   0.0% / 0 resp.

Who is the decision-maker for implementing a solution for this use case?

4 out of 138 answered

1   Senior management / leadership   75.0% / 3 resp.

2   TMF Management   50.0% / 2 resp.

3   Clinical Operations   25.0% / 1 resp.

4   Information Technology   25.0% / 1 resp.

5   Regulatory   0.0% / 0 resp.

6   Other   0.0% / 0 resp.

How do you currently do interim transfers of TMF content?

4 out of 138 answered

1
We have an integration with the destination system

50.0% / 2 resp.

2
We send it via email

25.0% / 1 resp.

3
We upload it into the destination system manually

25.0% / 1 resp.

4
We don't do interim transfers

0.0% / 0 resp.

5
Other

0.0% / 0 resp.
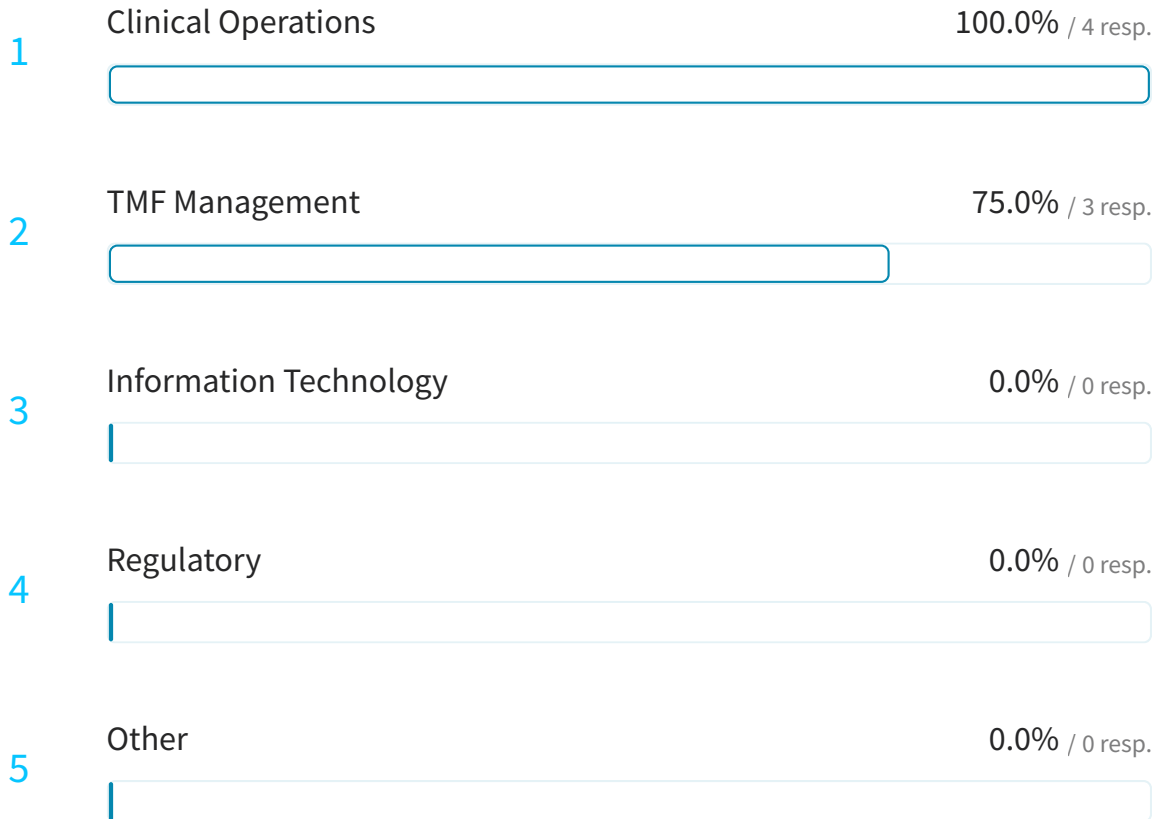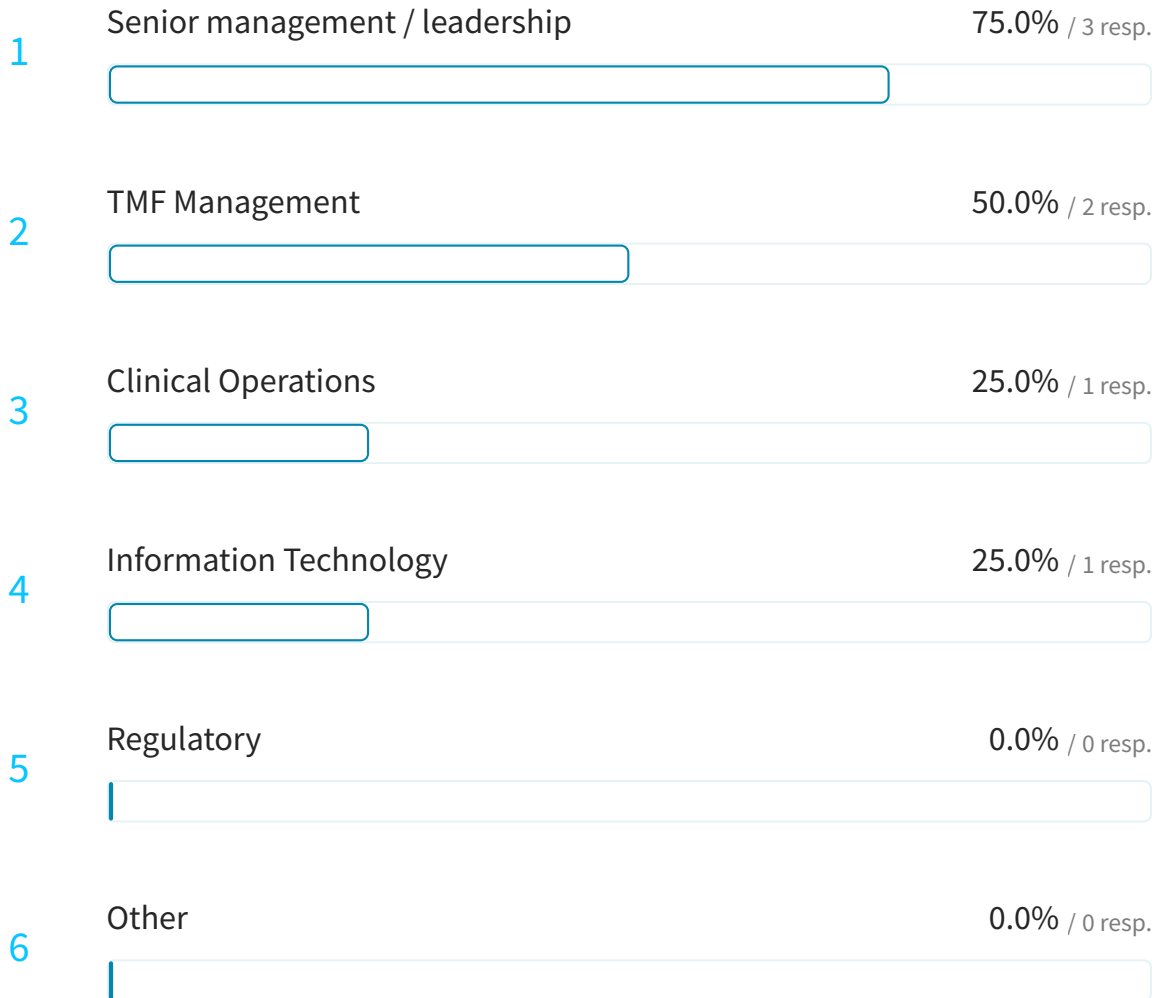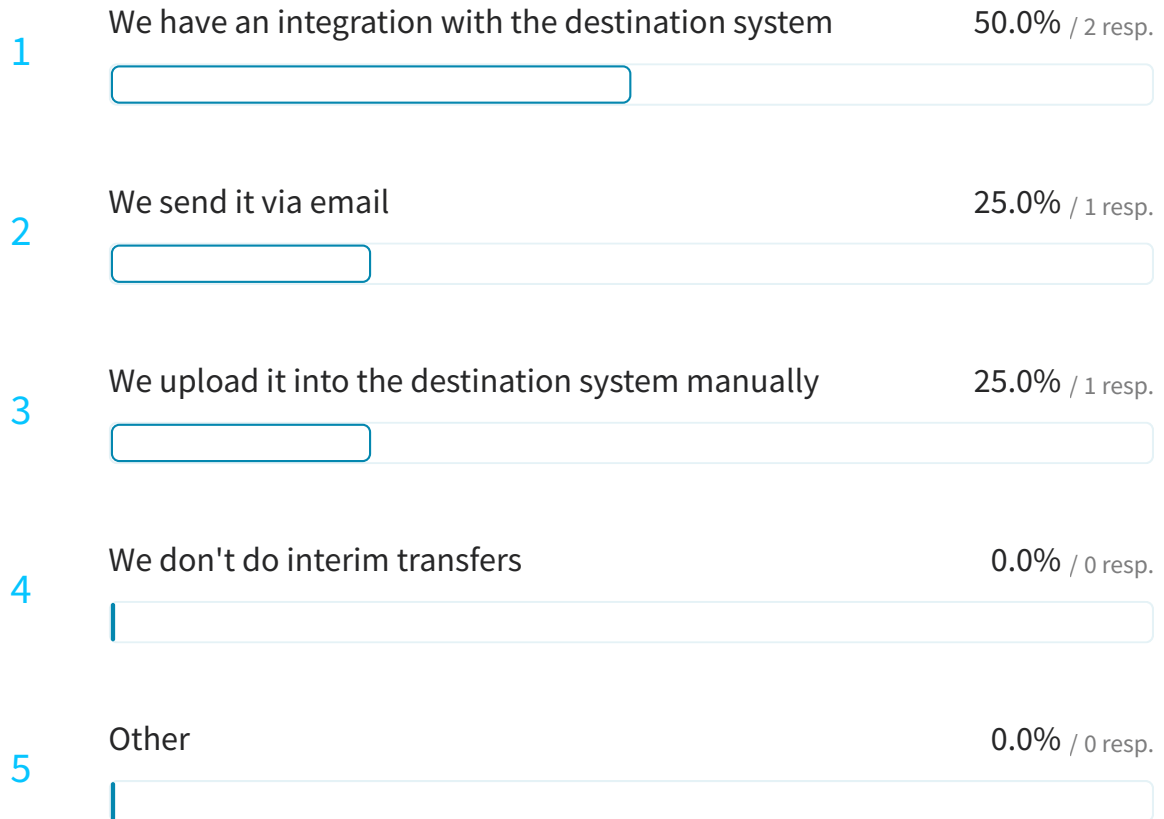
How critical would this use case be to the selection of an eTMF system or CRO?

4 out of 138 answered

3.2 Average rating

0.0%	25.0%	25.0%	50.0%	0.0%
0 resp.	1 resp.	1 resp.	2 resp.	0 resp.
1	2	3	4	5

Not critical at all   Highly critical

What would be the overall value to your organization if you were to use the eTMF-EMS to transfer interim TMF content?

out of 138 answered

Nobody answered this question yet

What specific value would this use case bring to your organization?

0 out of 138 answered

Nobody answered this question yet

Which part(s) of the organization would gain business value for this use case?

0 out of 138 answered

Nobody answered this question yet

Who is the decision-maker for implementing a solution for this use case?

0 out of 138 answered

Nobody answered this question yet

How do you currently do interim transfers of TMF content?

0 out of 138 answered

Nobody answered this question yet

How critical would this use case be to the selection of an eTMF system or CRO?

out of 138 answered

Nobody answered this question yet

Do you think this use case will bring value to your customers?

53 out of 138 answered

1   Yes   84.9% / 45 resp.

2   I do not know   13.2% / 7 resp.

3   No   1.9% / 1 resp.
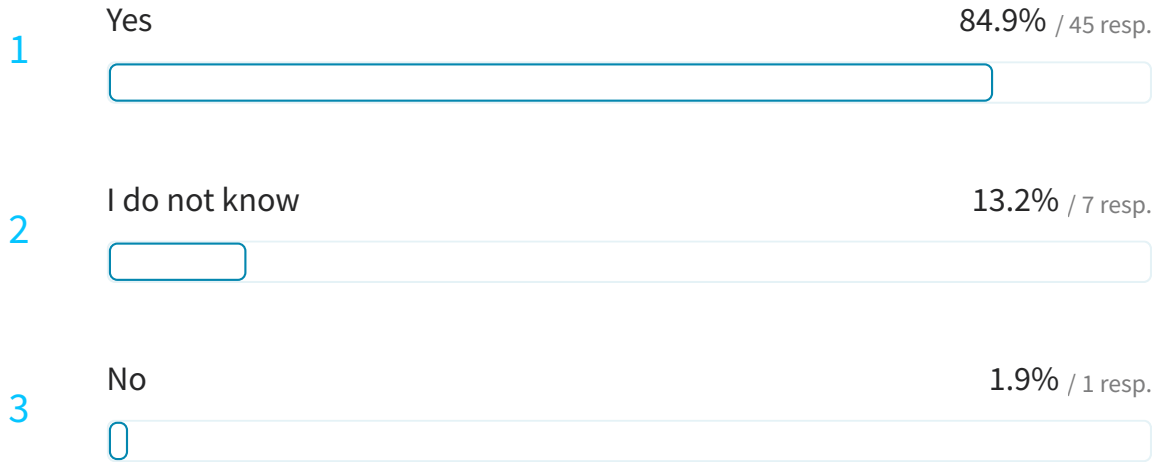
How would you rate the overall value your clients would realize by using the eTMF-EMS to automatically index and file content that is transferred to them?

45 out of 138 answered

4.2 Average rating

0.0%	2.2%	15.6%	40.0%	42.2%
0 resp.	1 resp.	7 resp.	18 resp.	19 resp.
1	2	3	4	5

Low Value

High Value
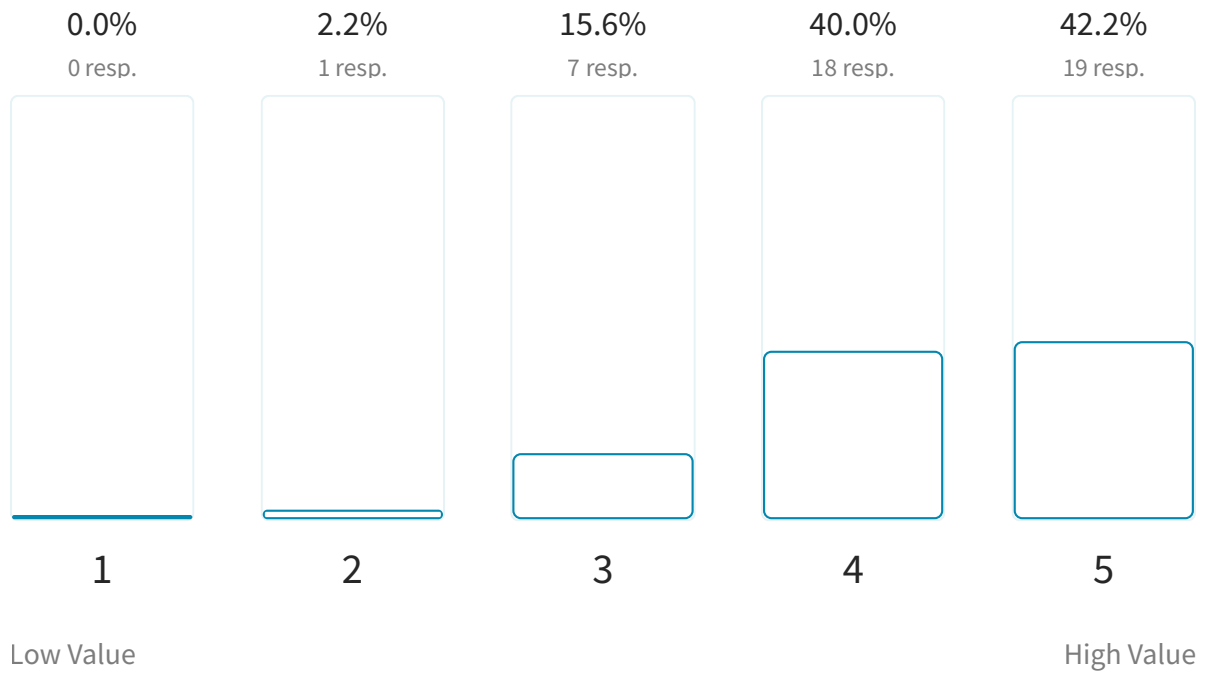
For this use case what is the most important value it would bring to your clients?

53 out of 138 answered
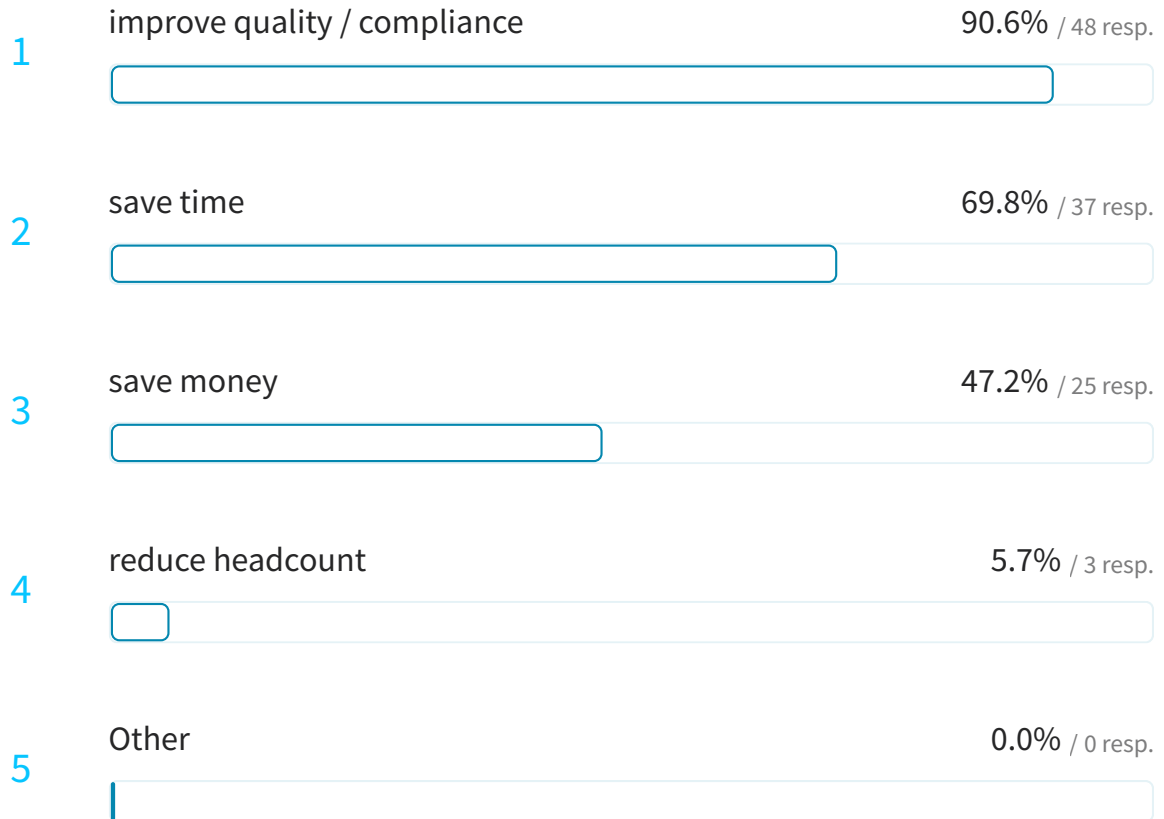
1   improve quality / compliance   90.6% / 48 resp.

2   save time   69.8% / 37 resp.

3   save money   47.2% / 25 resp.

4   reduce headcount   5.7% / 3 resp.

5   Other   0.0% / 0 resp.

Which part(s) of your clients organization would gain the most business value for this use case?

53 out of 138 answered

1   TMF Management   88.7% / 47 resp.

2   Clinical Operations   56.6% / 30 resp.

3   Regulatory   37.7% / 20 resp.

4   Information Technology   11.3% / 6 resp.

5   Other   1.9% / 1 resp.

Who is the decision-maker in your organization for developing a solution for this use case?

53 out of 138 answered

1 Senior management / leadership
79.2% / 42 resp.

2 eTMF Product Owner
26.4% / 14 resp.

3 Product Management
17.0% / 9 resp.

4 R&D Team
1.9% / 1 resp.

5 Other
3.8% / 2 resp.
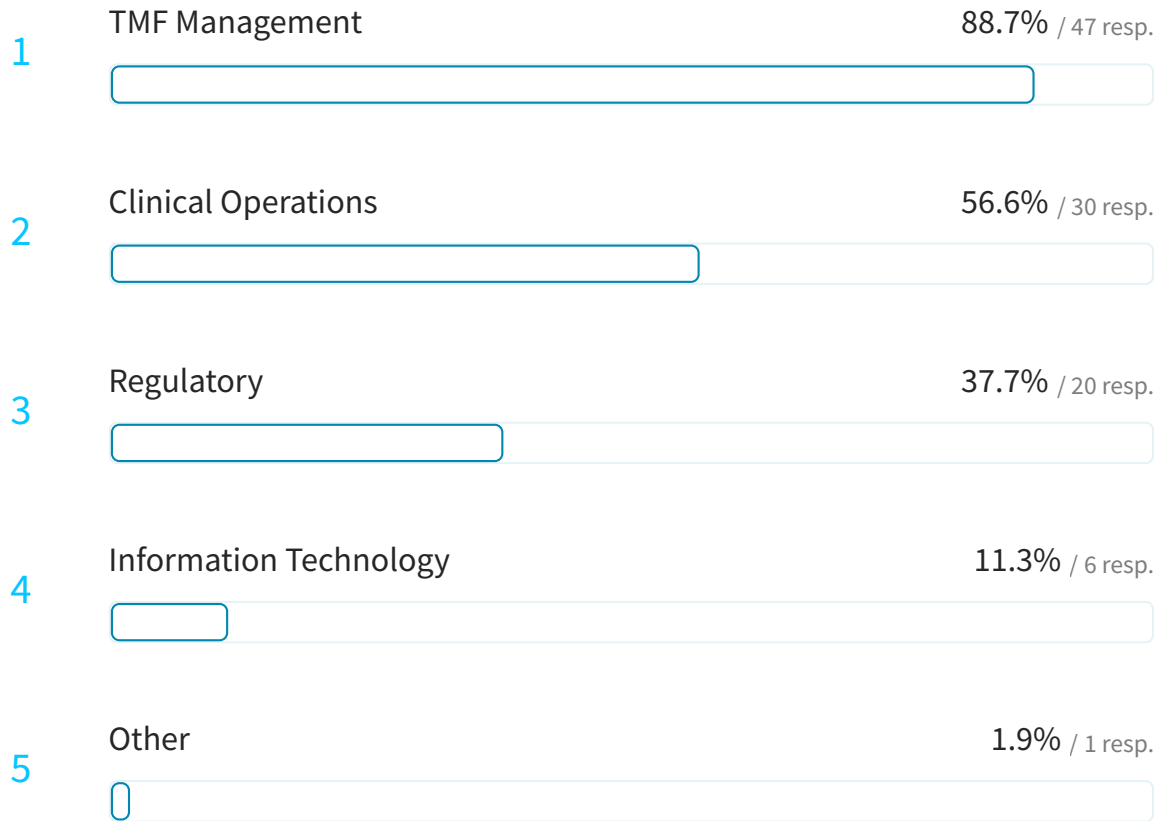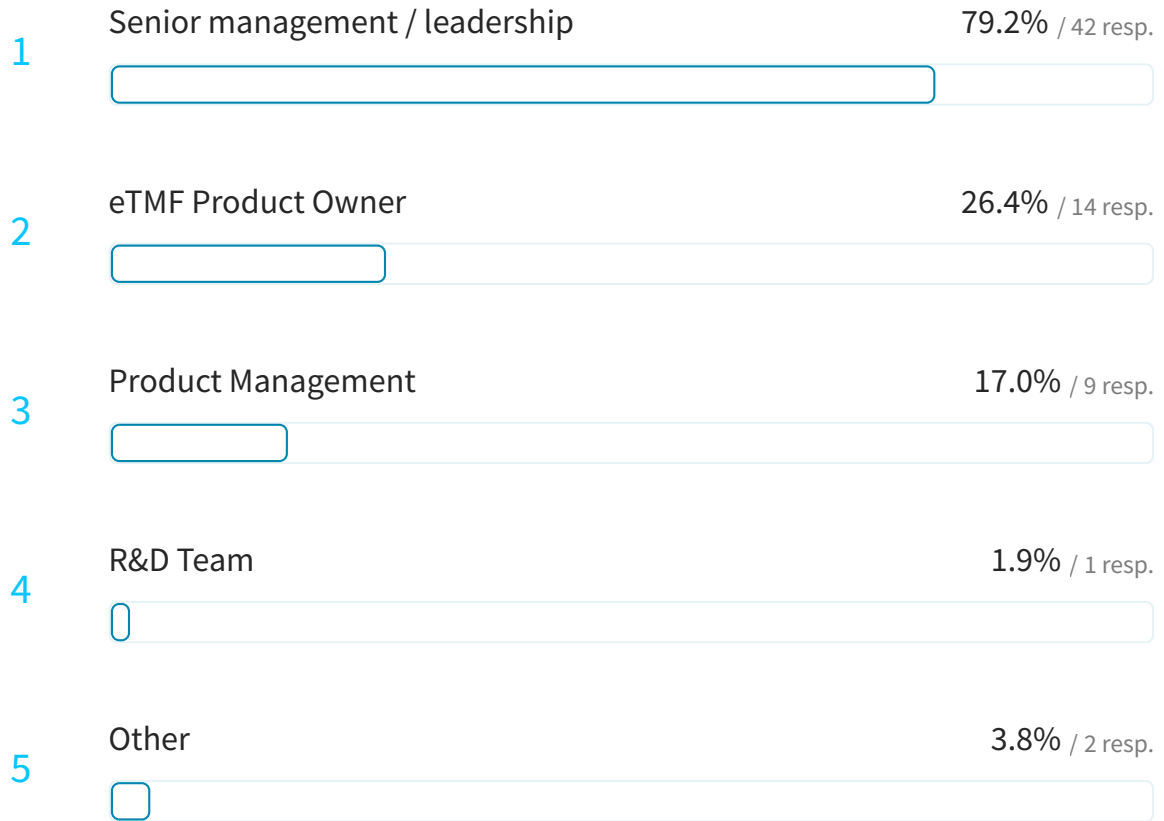
How do most of your clients load and index content transferred into your system?

53 out of 138 answered

1   They upload content and perform the indexing manually   45.3% / 24 resp.

2   They use a custom integration between the source and destination systems to automatically import, index, and file content   34.0% / 18 resp.

3   They tend to use other exchange standards to import, index and file content   11.3% / 6 resp.

4   Other   9.4% / 5 resp.
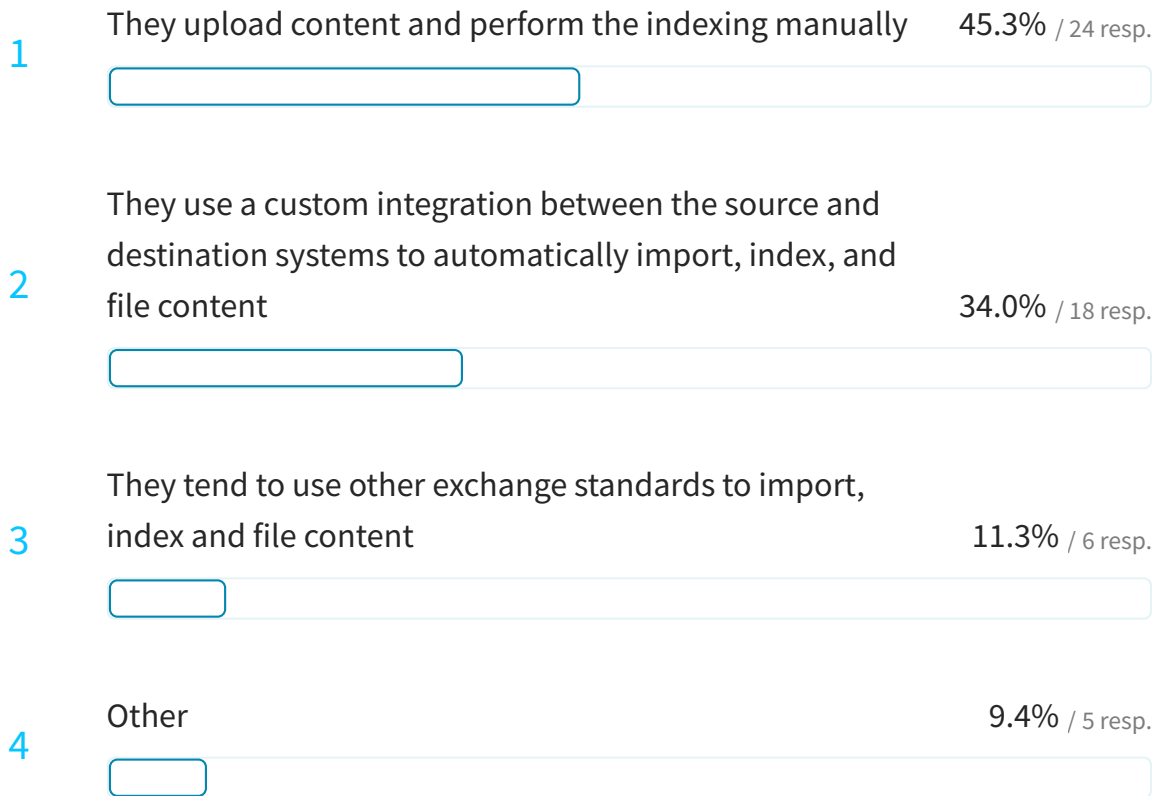
Do you believe that you would increase your chance of winning new clients if you offered the possibility of doing automated indexing using the eTMF-EMS?

53 out of 138 answered

1 Yes 90.6% / 48 resp.

2 No 9.4% / 5 resp.
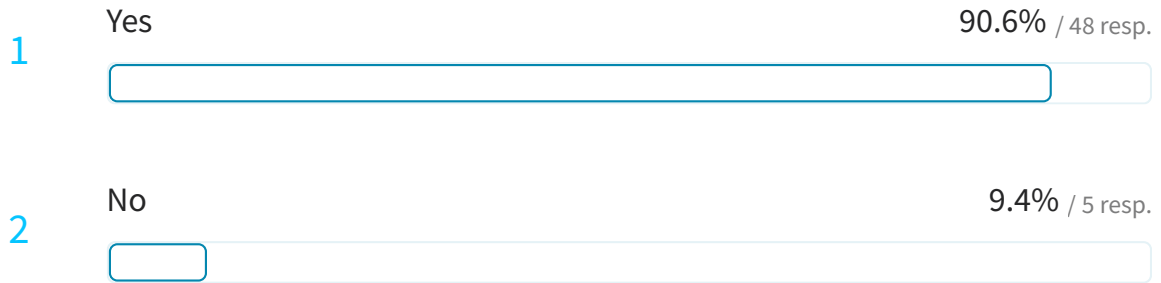
Do you think this use case will bring value to your customers?

35 out of 138 answered

1 Yes 85.7% / 30 resp.

2 I do not know 11.4% / 4 resp.

3 No 2.9% / 1 resp.
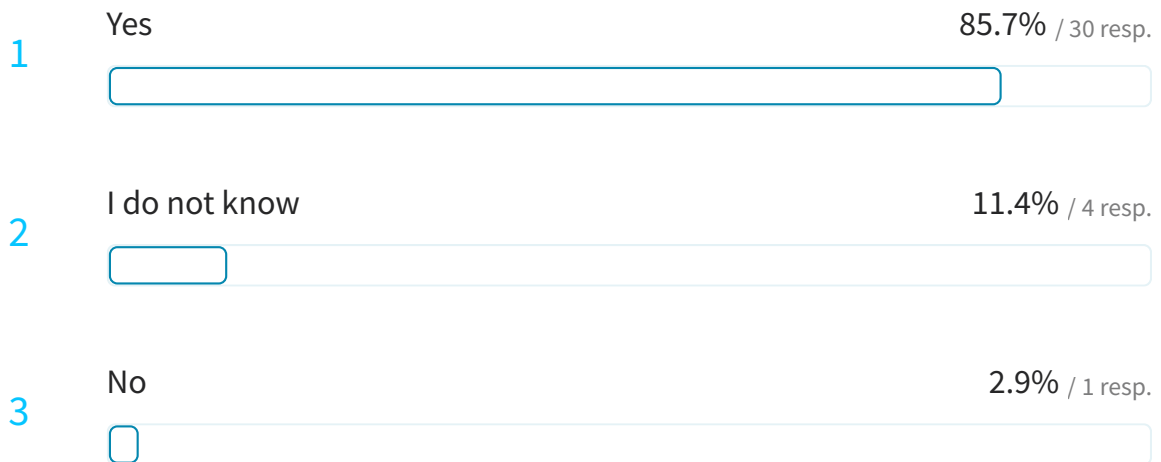
How would you rate the overall value your clients would realize by using the eTMF-EMS to migrate a complete study TMF as a batch without mapping filing structures or metadata?
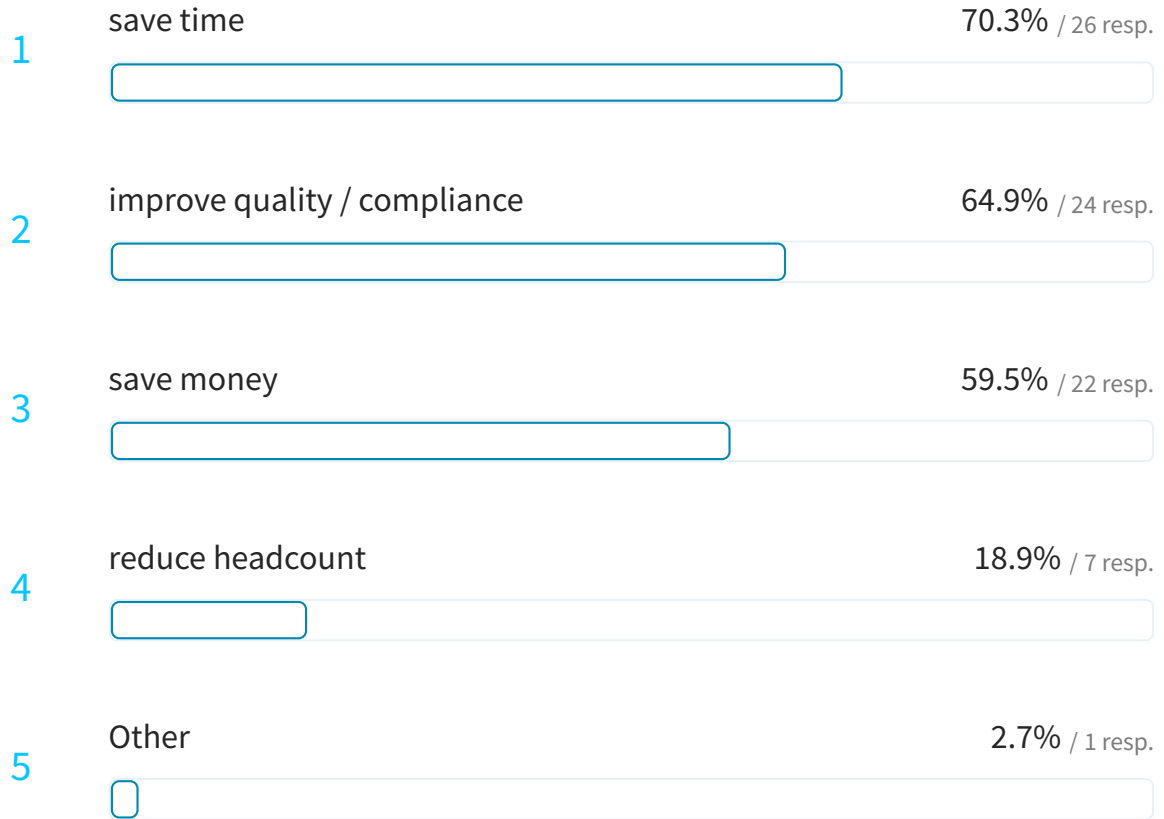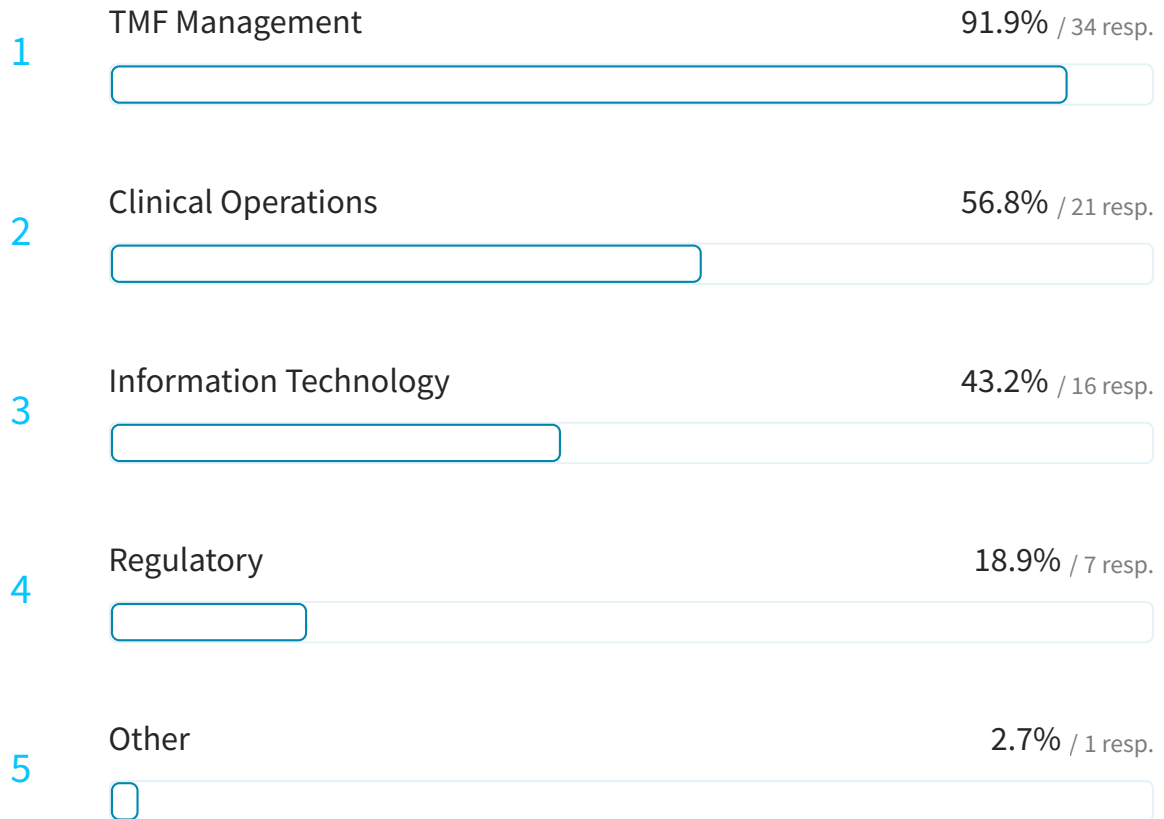
30 out of 138 answered

4.0 Average rating

3.3%	6.7%	16.7%	30.0%	43.3%
1 resp.	2 resp.	5 resp.	9 resp.	13 resp.
1	2	3	4	5

Low Value

High Value
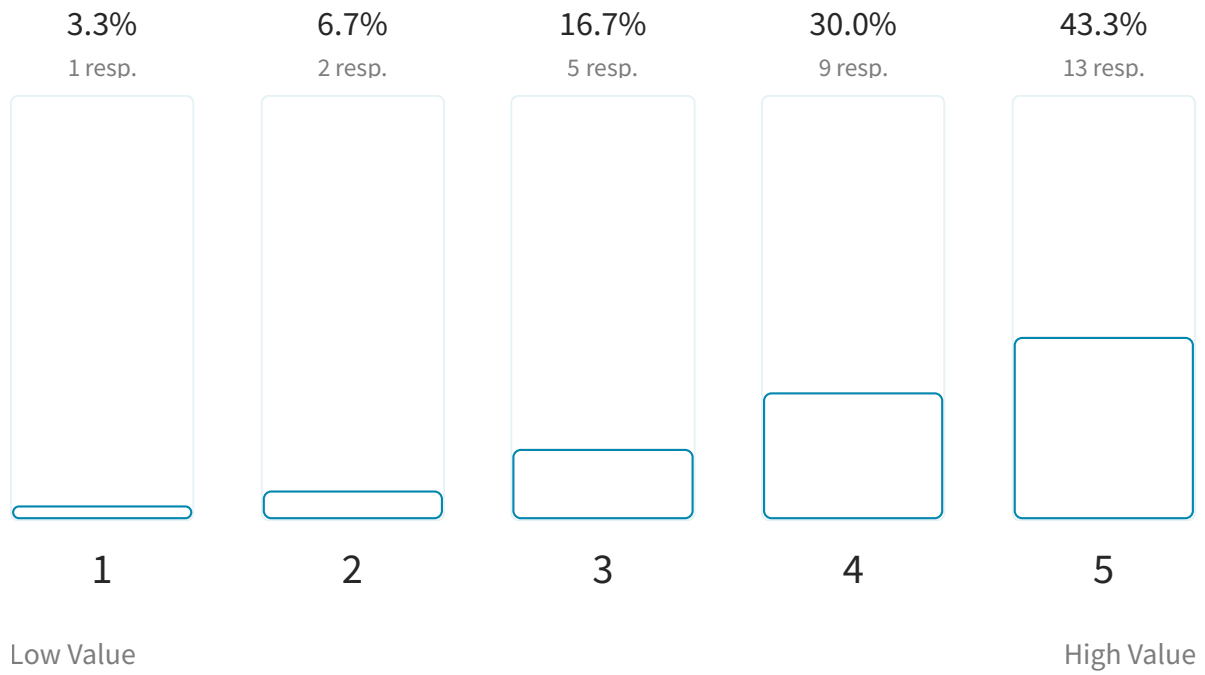
For this use case what is the most important value it would bring to your clients?

37 out of 138 answered

1   save time   70.3% / 26 resp.

2   improve quality / compliance   64.9% / 24 resp.

3   save money   59.5% / 22 resp.

4   reduce headcount   18.9% / 7 resp.

5   Other   2.7% / 1 resp.
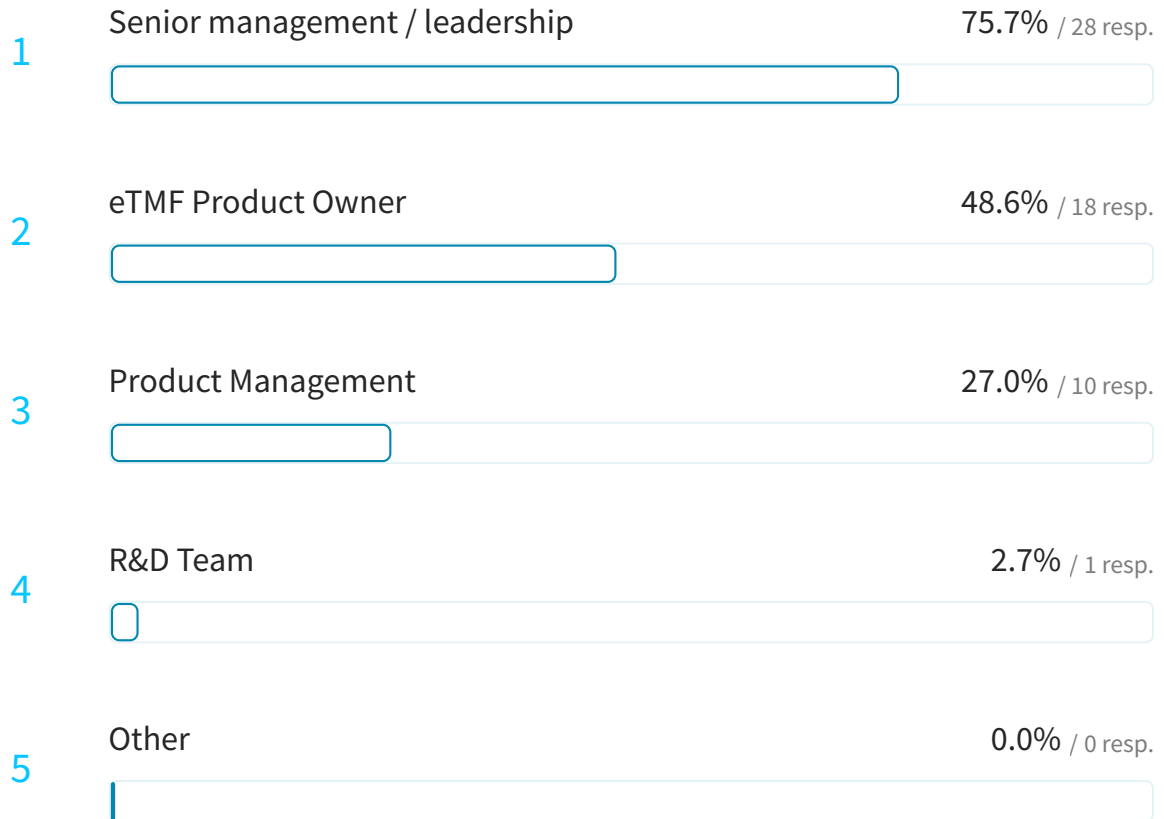
Which part(s) of your clients organization would gain the most business value for this use case?

37 out of 138 answered

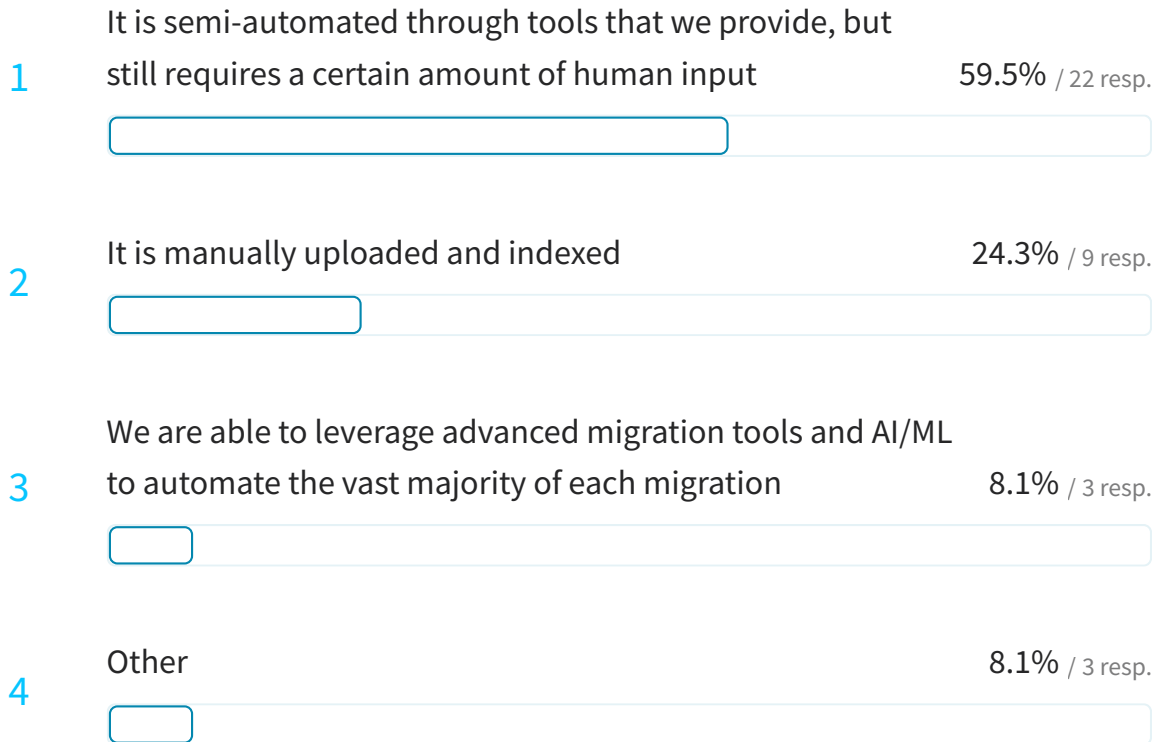1   TMF Management   91.9% / 34 resp.

2   Clinical Operations   56.8% / 21 resp.

3   Information Technology   43.2% / 16 resp.

4   Regulatory   18.9% / 7 resp.

5   Other   2.7% / 1 resp.

Who is the decision-maker in your organization for developing a solution for this use case?
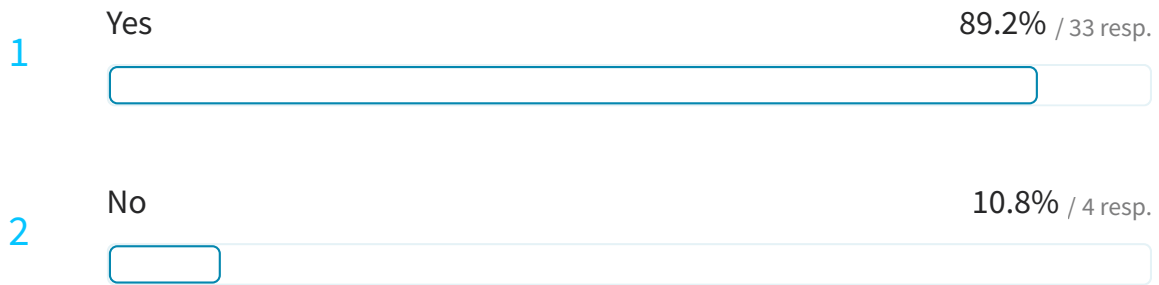
37 out of 138 answered

1   Senior management / leadership   75.7% / 28 resp.

2   eTMF Product Owner   48.6% / 18 resp.

3   Product Management   27.0% / 10 resp.

4   R&D Team   2.7% / 1 resp.

5   Other   0.0% / 0 resp.

How does your system currently allow clients to migrate TMF content?

37 out of 138 answered

1 It is semi-automated through tools that we provide, but still requires a certain amount of human input 59.5% / 22 resp.

2 It is manually uploaded and indexed 24.3% / 9 resp.

3 We are able to leverage advanced migration tools and AI/ML to automate the vast majority of each migration 8.1% / 3 resp.
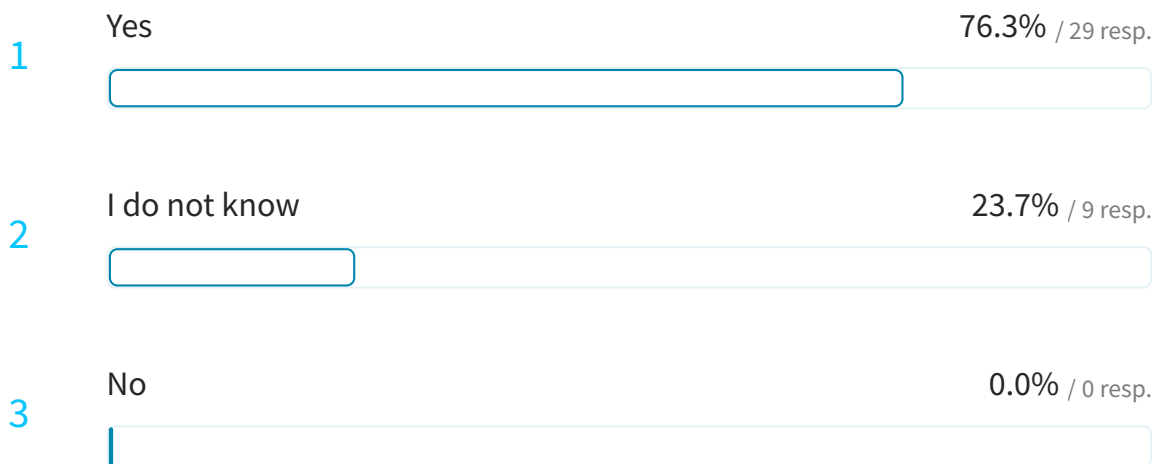
4 Other 8.1% / 3 resp.

Do you believe that allowing clients to quickly migrate TMFs with minimal human input due to the use of the eTMF-EMS would give you a competitive edge in the market?

37 out of 138 answered

1   Yes   89.2% / 33 resp.

2   No   10.8% / 4 resp.

Do you think this use case will bring value to your customers?

38 out of 138 answered

1   Yes   76.3% / 29 resp.

2   I do not know   23.7% / 9 resp.

3   No   0.0% / 0 resp.
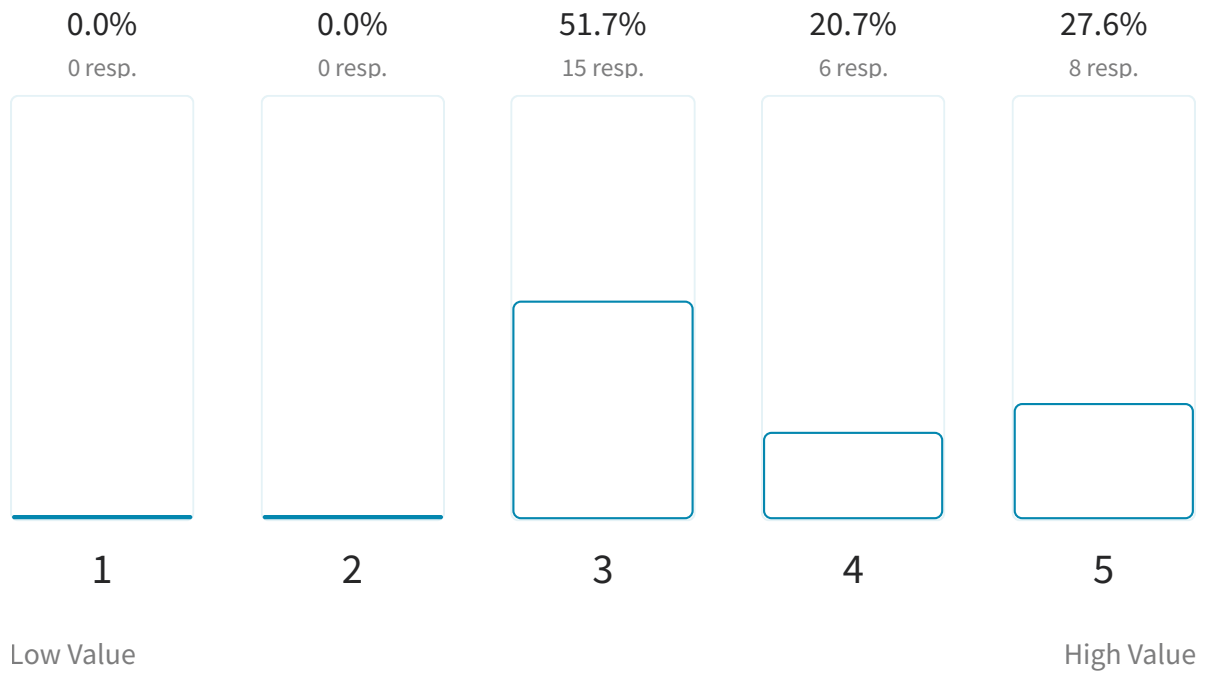
How would you rate the overall value your clients would realize by using the eTMF-EMS format for long-term archiving of TMF content?

29 out of 138 answered

3.8 Average rating

0.0%	0.0%	51.7%	20.7%	27.6%
0 resp.	0 resp.	15 resp.	6 resp.	8 resp.
1	2	3	4	5

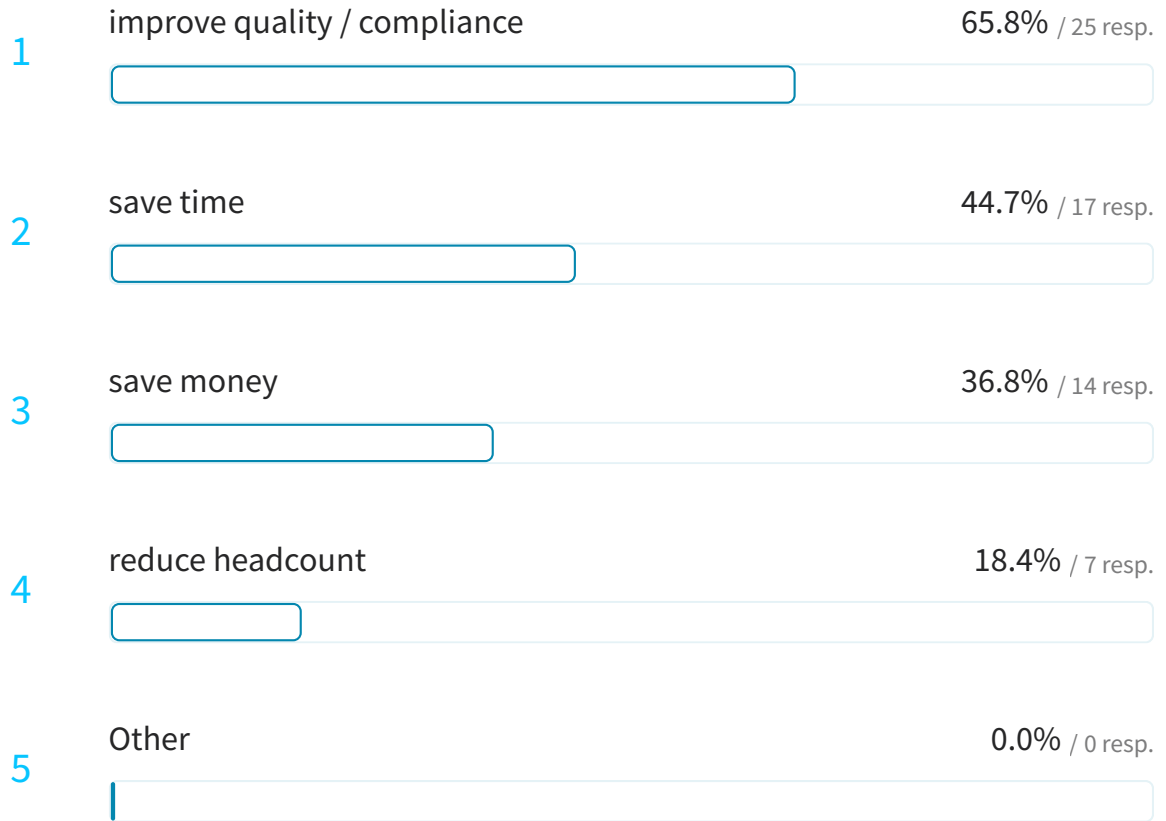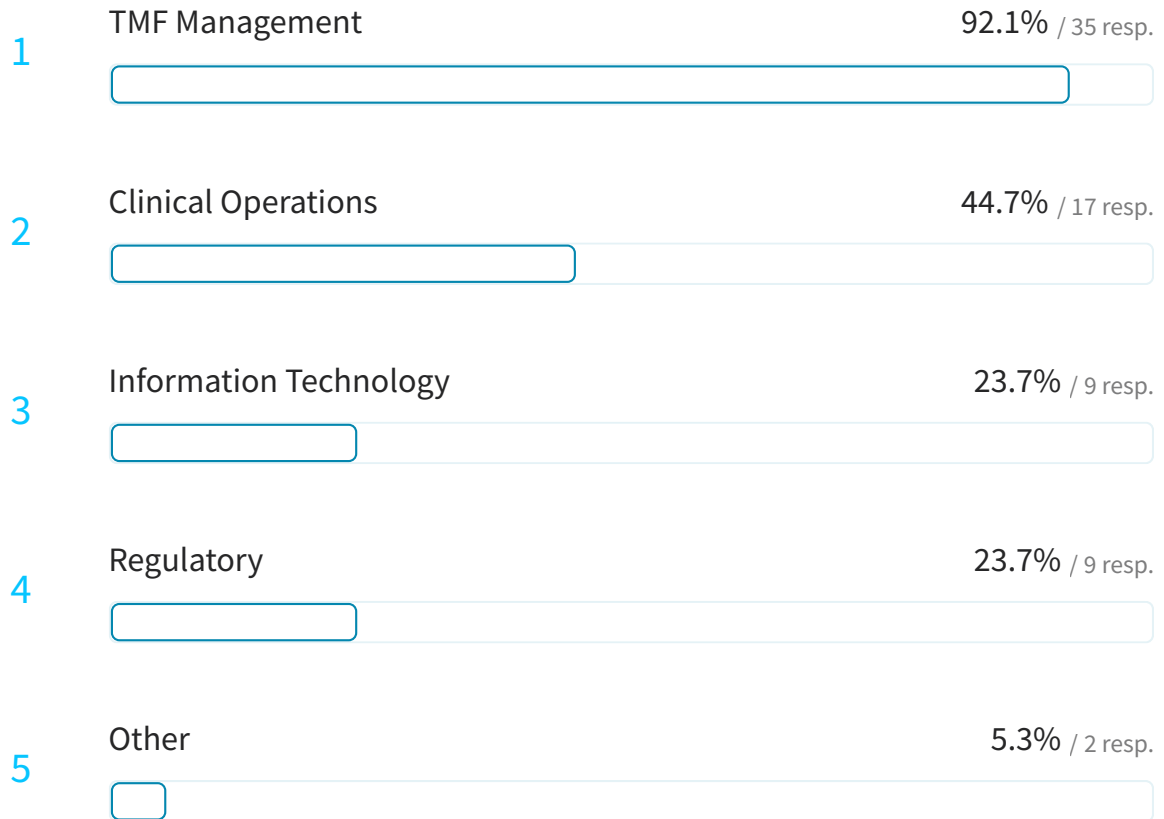Low Value   High Value

For this use case what is the most important value it would bring to your clients?
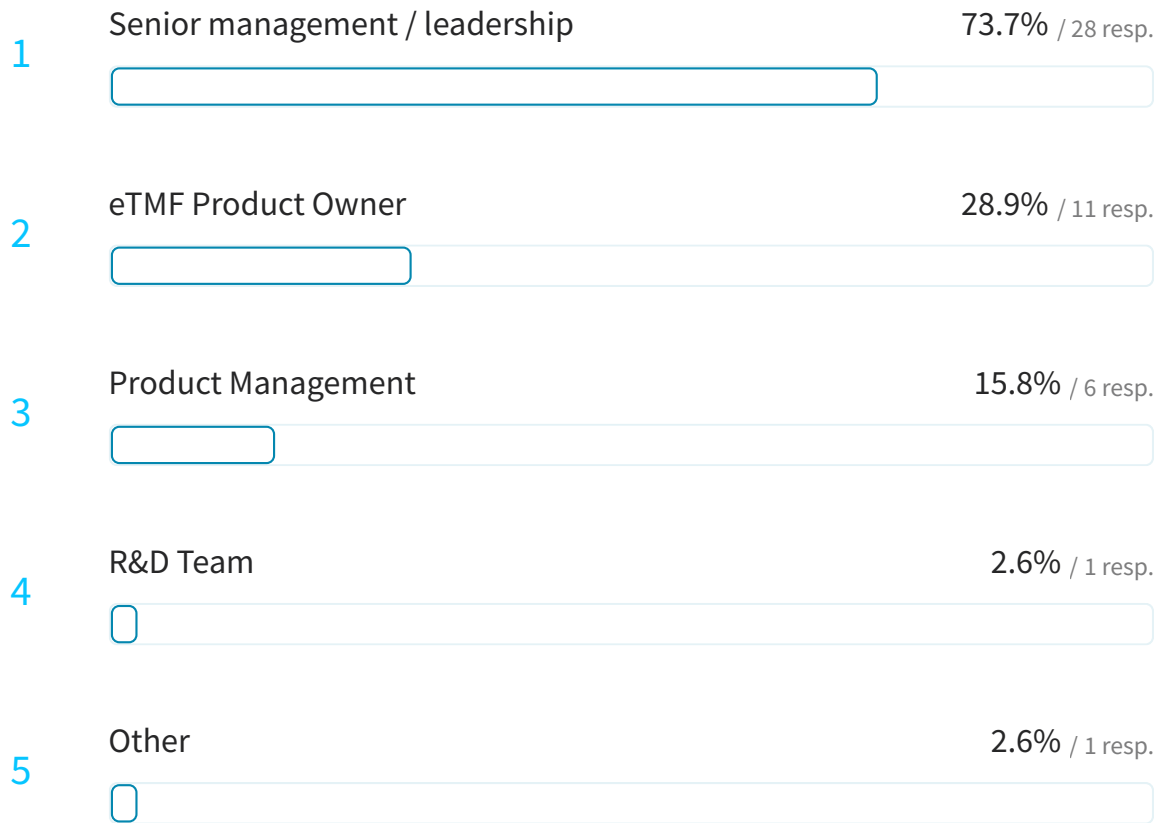
38 out of 138 answered

1
improve quality / compliance
65.8% / 25 resp.

2
save time
44.7% / 17 resp.

3
save money
36.8% / 14 resp.

4
reduce headcount
18.4% / 7 resp.

5
Other
0.0% / 0 resp.

Which part(s) of your clients organization would gain the most business value for this use case?

38 out of 138 answered

1   TMF Management   92.1% / 35 resp.

2   Clinical Operations   44.7% / 17 resp.

3   Information Technology   23.7% / 9 resp.

4   Regulatory   23.7% / 9 resp.
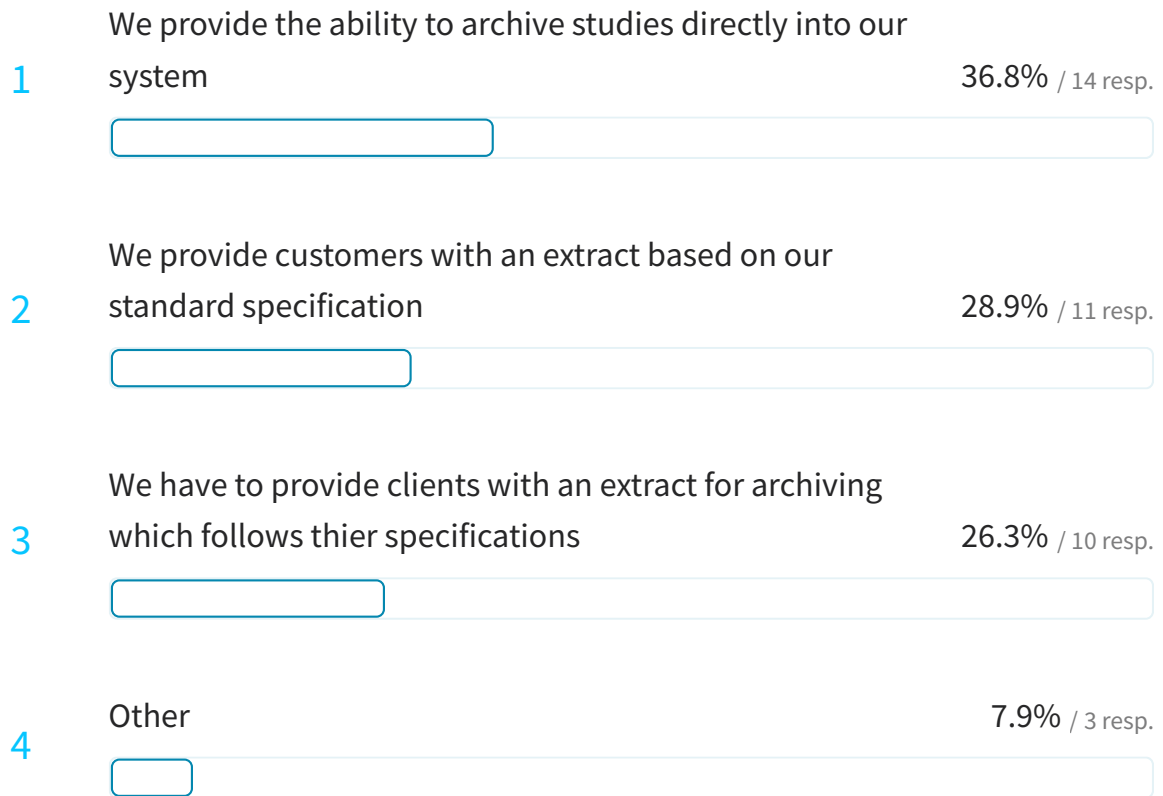
5   Other   5.3% / 2 resp.

Who is the decision-maker in your organization for developing a solution for this use case?

38 out of 138 answered

1   Senior management / leadership   73.7% / 28 resp.

2   eTMF Product Owner   28.9% / 11 resp.

3   Product Management   15.8% / 6 resp.

4   R&D Team   2.6% / 1 resp.

5   Other   2.6% / 1 resp.

How do your clients currently request extracts to archive TMF content within your system?

38 out of 138 answered

1   We provide the ability to archive studies directly into our
    system   36.8% / 14 resp.

2   We provide customers with an extract based on our
    standard specification   28.9% / 11 resp.

3   We have to provide clients with an extract for archiving
    which follows thier specifications   26.3% / 10 resp.

4   Other   7.9% / 3 resp.

Do you typically see the eTMF-EMS being leveraged as a format for archive extracts in the future?

38 out of 138 answered

1 Yes
63.2% / 24 resp.

2 No
36.8% / 14 resp.
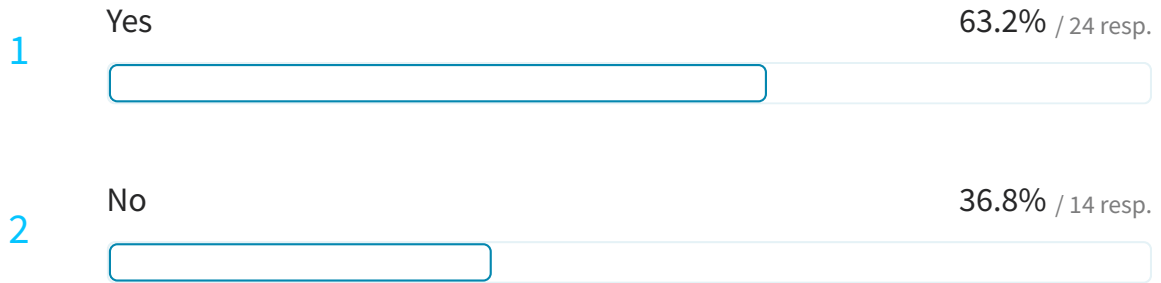
Would you like to receive a copy of the survey results?

138 out of 138 answered

1 Yes
80.4% / 111 resp.

2 No
19.6% / 27 resp.