The adoption of EU MDR and IVDR has greatly increased the demand for systematic literature reviews. In combination with the ever-increasing volumes of literature published each year, the workload of regulatory writers in the medical devices and in vitro diagnostics industries is soaring.

The purpose of this article is to investigate current practices and the use of software tools by medical writers and other professionals involved in systematic literature reviews for medical devices and in vitro diagnostics using an internet survey.

Methods
Survey details
An anonymous, online survey (see Appendix 1) was conducted using SurveyMonkey (https://www.surveymonkey.com/) from April 3 to May 9, 2023. All EMWA members were invited to participate via email. A reminder email was sent shortly before the closing date. To solicit additional responses, members were encouraged to share the link and the link to the survey was also posted on LinkedIn (https://www.linkedin.com/).

Data processing
The survey tool allows submission of incomplete responses, but querying of missing or inconsistent responses was not possible. A data cleaning process removed obviously inconsistent or irrelevant responses, and additional categorical variables were created for free text responses. When a range was provided for the time spent on a literature review, the highest estimate was used for analysis. Responses in weeks, days, or months were converted to hours using the assumption of 8 hours/day, 40 hours/week, and 184 hours/month. A categorical variable was added to indicate whether respondents provided a time estimate and, if not, whether this was because the question did not state the volume/size of the literature review or because respondents were not able to estimate the time needed for a literature review.

The number of software packages used per respondent was calculated per type of software (word processor, spreadsheet, reference manager, PDF software, graphical software, and databases) and overall.

Statistical analysis
Descriptive statistics included frequencies and percentages for categorical variables, and mean, standard deviation, median, and range for numerical variables.

Statistical analyses were performed using SPSS 28.0 (IBM Corp, Armonk NY, USA). The Kolmogorov-Smirnov test indicated that numerical variables were not normally distributed. Therefore, non-parametric tests were used: Mann Whitney U-test and Kruskal-Wallis H-test, as appropriate. Bonferroni corrections were used for multiple comparisons. For categorical variables, Pearson’s chi square test was used. A value of P<0.05 was considered significant.

Results and discussion
Characteristics of survey respondents
The survey was completed by 125 respondents (Figure 1) from 31 different countries, with respondents from Germany (n=22, 17.6%), France (n=9, 7.2%), Belgium (n=9, 7.2%), United States (n=8, 6.4%), the UK (n=7, 5.6%), and Canada (n=7, 5.6%) accounting for more than half (n=69, 55.2%) of the responses.

Responders were mostly female (n=89, 71.2%), and working as employees (n=78, 62.4%). Freelancers made up 23.2% (n=29) of the respondent population, whereas 8.8% (n=11) are in a hybrid employment situation, and 5.6% (n=7) of the respondents are small business owners.

Respondents predominantly conduct literature reviews as medical writers (n=73,
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Literature review process

Only 6% of respondents conduct systematic literature reviews using an automated process, whereas 35% use a partially automated process and 59% use a fully manual process without specific software or tools for conducting literature reviews (Figure 2). Of the respondents who use specific software tools for at least part of the literature review process (n=40, 32%), 19 (47.5%) use a commercially available desktop or self-hosted software package, 15 (37.5%) use a software-as-a-service (SaaS) platform, whereas 6 (15.0%) use a custom or self-created tool or application. About a third of respondents perform different steps of the literature review in duplicate. Screening in duplicate was reported by 38.1%, appraisal in duplicate by 37.1%, and data extraction in duplicate by 27.8% of respondents.

A valid numerical time estimate for conducting new or updated literature reviews was provided by 78 respondents. Time estimates averaged 84.8 hours (SD 71.2, IQR 37.5–105.0) for new literature reviews and 45.9 hours (SD 70.4, IQR 13.75–50) for updates of literature reviews. Eight respondents reported time estimates of at least 200 hours for new...
literature reviews (the maximum being 500 hours), whereas 14 respondents reported typically spending less than 8 hours on a new literature review. These data either point to domains where no or very limited data are available or to possible misreporting where the unit intended by the respondent may have been days or weeks.

Several \((n=10, 8\%)\) respondents correctly indicated that the time needed is dependent on the volume of literature retrieved, and the survey question did not contain a size indication for the retrieved literature. The question on the time needed to perform a new literature review or an update to a literature review was skipped by 35 (28\%) respondents, and of those who did not provide a valid numerical estimate, 10 (8\%) indicated volume of retrieved literature as reason, whereas 4 (3.2\%) indicated they had no idea of the time typically spent on a literature review.

The number of hours spent on either new or updated literature reviews did not differ significantly by employment type, role, or level of experience. Time estimates did not differ significantly according to the type of process used (manual, partially automated, or automated) for either new or updated literature reviews, but the difference neared significance for new literature reviews \((P=0.072)\) (Figure 2).

**Use of dedicated literature review software**

Respondents’ answers on their use of and familiarity with software tools specifically intended for conducting systematic literature reviews are displayed in Table 1. On average, 4.6\% of respondents were currently using one of the software tools in the survey; these software tools had been used in the past by 3.4\% of respondents, 2.2\% were planning to use them in the near future, 12.7\% were aware of their existence, and 77.1\% of respondents were unfamiliar with them. DistillerSR is the most widely used and known package. Medboard and Polarion were named as additional software packages by one respondent each via the “Other (please specify)” option.

**Other software packages**

Respondents used a median of 5 (interquartile [IQR] 4–7, range 0–15) other, general purpose software packages. The total number of software tools used was significantly lower for respondents who did not use a manual process or used a SaaS package for conducting literature reviews (Kruskal-Wallis \(P=0.03\)), whereas respondents with custom/self-made applications reported using a higher number of database applications \((P=0.009)\).

Figure 3 presents an overview of the most frequently used software tools in different categories. Word processing software is used by 89.4\% of respondents, spreadsheets by 86.9\%, reference management software by 73.2\%, PDF handling software by 79.9\%, graphical software by 61\%, and database software by 18.3\%.

Microsoft Office tools are the most frequently used software packages in every category in which they are represented, and Acrobat is dominant for PDF handling. Two respondents indicated using the Mac OS Preview application.
Figure 3. Current use of other software tools

Bars indicate the % of responses.

Abbreviations: MS, Microsoft; PDF, portable document format; WPS, Writer, Presentation, and Spreadsheets

Table 1. Familiarity with software tools for systematic literature reviews

<table>
<thead>
<tr>
<th>Software Tool</th>
<th>Currently using</th>
<th>Used in the past</th>
<th>Planning to use in the near future</th>
<th>Know it exists/heard or read about it</th>
<th>Not familiar with it</th>
</tr>
</thead>
<tbody>
<tr>
<td>Covidence</td>
<td>3.7% (3)</td>
<td>3.7% (3)</td>
<td>2.4% (2)</td>
<td>13.4% (11)</td>
<td>76.8% (63)</td>
</tr>
<tr>
<td>Rayyan</td>
<td>8.5% (7)</td>
<td>2.4% (2)</td>
<td>1.2% (1)</td>
<td>3.7% (3)</td>
<td>84.2% (69)</td>
</tr>
<tr>
<td>DistillerSR</td>
<td>8.5% (7)</td>
<td>7.3% (6)</td>
<td>1.2% (1)</td>
<td>22.0% (18)</td>
<td>81.0% (50)</td>
</tr>
<tr>
<td>Giotto Compliance</td>
<td>1.2% (1)</td>
<td>1.2% (1)</td>
<td>2.4% (2)</td>
<td>15.9% (13)</td>
<td>79.3% (65)</td>
</tr>
<tr>
<td>Systematic Review Accelerator</td>
<td>1.2% (1)</td>
<td>2.4% (2)</td>
<td>3.7% (3)</td>
<td>8.5% (7)</td>
<td>84.2% (69)</td>
</tr>
</tbody>
</table>

The question was answered by 82 respondents. Additional software packages named via the “Other (please specify)” option of this question were Medboard and Polarion, each named by one user.
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Challenges

Keeping up with large volumes of information
Ensuring quality: reducing the number of errors
Managing the literature review process efficiently
Defining the scope and searches
Ensuring the traceability of the literature review results
Getting literature done on time
Other (please specify)

Contributions of literature review software

Process improvement
Data extraction
Time saving
Search setup and validation
Traceability
Error reduction
All in one
Analysis/reporting
User friendliness

Figure 4. Current challenges and most valuable potential contributions of software to the literature review process

Bars indicate the % of responses.

for handling PDFs. In addition to the graphical software listed in the survey, three respondents use MS Word for creating Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) charts, three others indicate that this functionality is built into the literature review software they use, and one respondent reported not creating PRISMA charts.

The role of software in the literature review process

The main challenges perceived by respondents in conducting systematic literature reviews are shown in Figure 4. Responses in the “Other (please specify)” category were getting full texts of included articles and meeting client/employer expectations while maintaining quality.

Data extraction was reported as both the most time-consuming and error-prone step of the literature review process. Data extraction, screening, and data analysis were indicated as the three most important aspects where the use of software tools could most help to reduce the error rate and improve traceability of literature review results. Process improvement, improvement of data extraction, and time saving were the most valuable topics addressed by systematic literature review software, according to respondents (Figure 4).

Limitations

Some of the limitations are inherent to the nature of anonymous internet surveys. It is hard to estimate how representative the respondent population is and impossible to query missing or inconsistent results. The question on the estimated time needed for conducting a systematic literature review did not include a standard volume of retrieved literature, causing several respondents not to provide a valid numerical estimate.

As the objective of the study was to investigate current practices and familiarity with existing software tools, the survey did not question the motivation or reason for using or not using certain systems. Questions on specific features respondents require or look for in systematic literature software packages were not included either.

Although the SurveyMonkey tool used to distribute the survey prevents a respondent taking the survey more than once from the same device, it cannot check whether the same respondent filled out the survey from multiple devices.

Conclusion

The majority of respondents (59%) conduct systematic literature reviews manually, without the aid of dedicated software packages, and most (61%–84%) are unfamiliar with the literature review tools queried in the survey. Data extraction was both the most time-
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Disclosures and conflicts of interest
The author declares no conflicts of interest.

Disclaimer
Any interpretations and opinions in this article are the author’s and are not necessarily endorsed by EMWA.

Data availability statement
For inquiries about data and other supplemental information, please contact the corresponding author.

References


Author information
Veerle Persy, MD, PhD, is owner of Hugin Mugin Research and has provided consultancy, medical writing, and data management services since 2007. She is a member of the EMWA Medical Devices Special Interest Group and has a special interest in evidence synthesis, usability of scientific information, and knowledge management.
Appendix
Appendix 1. Survey questions

Demographics

What is your gender?
- a. Female
- b. Male
- c. Non-binary
- d. Prefer not to say

In what country do you live? (List of countries to select from)

What is your employment type?
- a. Freelancer
- b. Employee
- c. Hybrid (a mix of employed and freelance)
- d. Small business owner (<10 salaried or subcontracted team members)

In what role do you perform systematic literature reviews?
- a. Medical Writer
- b. Researcher
- c. Clinical/Regulatory Affairs Manager
- d. Other (specify)

How many years of experience do you have in your current role?
- a. <3
- b. 3–5
- c. 6–10
- d. >10

Process

Are you currently conducting your literature reviews manually?
- a. Yes  b. No  c. Partially

What tool do you use for your literature reviews?
(Only available when answer to previous question was not a. Yes)
- a. Commercially available desktop/self-hosted software
- b. Commercially available web application (SaaS)
- c. Custom/Self-made application(s)

Do you perform screening in duplicate (every paper screened by two people)?
- a. Yes  b. No

Do you perform appraisal in duplicate?
- a. Yes  b. No

Do you perform data extraction in duplicate?
- a. Yes  b. No

Time

How many hours do you (and your team) typically spend in total on a (new) systematic literature review?

How many hours do you (and your team) typically spend on an update of a systematic literature review?

Use of dedicated literature review software/tools

How familiar are you with the following platforms for conducting systematic literature reviews?
- Covidence
- Rayyan
- DistillerSR
- Giotto Compliance
- Systematic Review Accelerator
- Other (please specify)

- a. Currently using
- b. Used in the past
- c. Planning to use in the near future
- d. Know it exists (heard or read about it)
- e. Not familiar with it

Use of other software tools

Which other software tools do you use in for conducting a literature review? (check all that apply)

Word processor
- MS Word
- Google Docs
- LibreOffice Writer
- WPS Writer
- Scrivener
- None of these

Spreadsheets
- MS Excel
- Google Sheets
- LibreOffice Calc
- WPS Spreadsheet
- None of these

Reference management software
- EndNote
- Mendeley
- Zotero
- SciWheel
- Paperpile
- Papers
- RefWorks
- Citavi
- Qiqqa
- Docear
- None of these

PDF software
- Adobe Acrobat Reader
- Adobe Acrobat
- Foxit PDF Reader
- Nitro
- PDF-Xchange
- WPS PDF Reader
- None of these

Graphical/flowchart software
- MS PowerPoint
- MS Visio
- Drawio
- LucidChart
- SmartDraw
- Adobe InDesign
- MindManager
- None of these

Database
- MS Access
- FileMaker Pro
- LibreOffice Base
- OpenOffice Base
- Memento Database
- Airtable
- None of these

Abbreviations: MS, Microsoft; PDF, portable document format; SaaS, software as a service; WPS, Writer, Presentation, and Spreadsheets