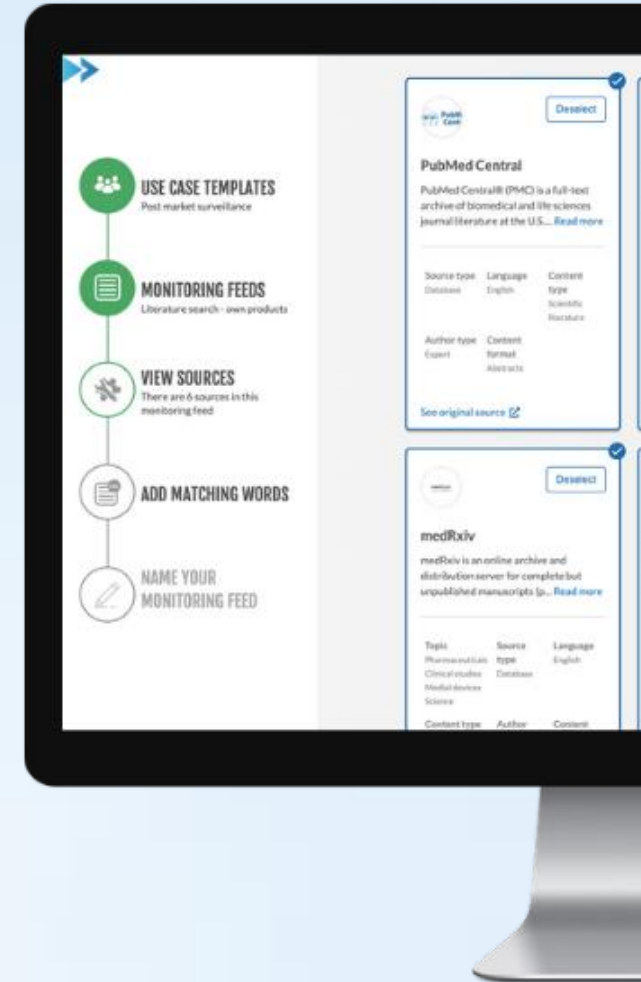# Mitigating Risk Through Automation of Regulatory Intelligence and Insights

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26 April 2021 | 11:00-12:00 (GMT+1)

Introductions

- ## Nik Wells
  Nik has more than 20 years of experience in the bio-pharmaceutical industry and has worked with clients of all sizes, where he has gained expertise in the field of Regulatory Affairs. In 2020 Nicholas joined Hoodin as a Partner Manager responsible for the UK market.
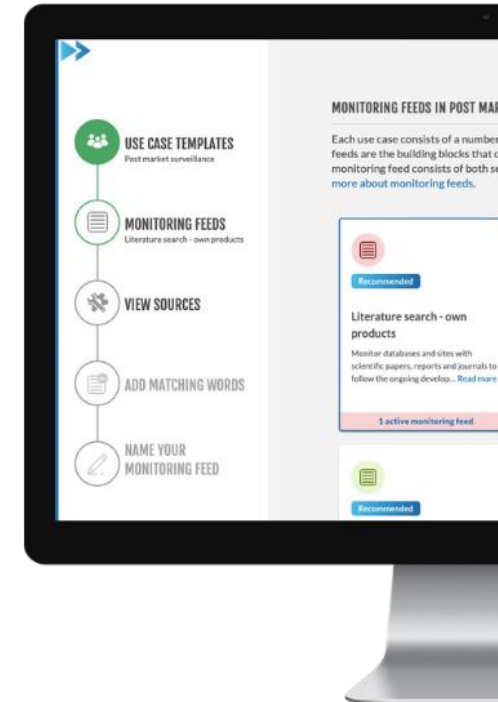

- ## Marcus Emne
  Marcus is the founder and CEO of Hoodin, and has extensive experience in building and developing international companies.

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Today's Webinar Learnings

1 What content monitoring is and its importance in regulatory affairs.

2 Risks of failing to adequately monitor content.

3 Understand how content monitoring can be automated.

4 Benefits of automating content monitoring.

5 Tips on creating effective content monitoring strategies to mitigate risks.

6 Understand other areas of the industry where automated content monitoring can be used.

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Content Monitoring in Regulatory Affairs

Regardless of our regulatory role **we currently monitor** content for:

Changes in regulations   Competitor intelligence   Regulatory news and trends

Developing strategies   Personal development

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Importance of content monitoring

To be an efficient and effective regulatory individual or team **we must stay current**

As a Regulatory Individual	As a Regulatory Team
Create and deliver effective regulatory strategies	Provide reliable cross-functional input
Contribute effectively to your team	Contribute effectively to development strategy
Develop and maintain expertise	Educate team and other departments
Educate others	Help to shape internal and external policy and direction
Develop your skills and career	Reduce costs from mistakes or inefficiency

Content monitoring plays a role in **ALL** of the above and more

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Importance of keeping up to date

Failing to **continuously monitor relevant content** and **stay current** can be costly

Leaving you behind the "knowledge" curve

Leading to weak/poor regulatory strategies

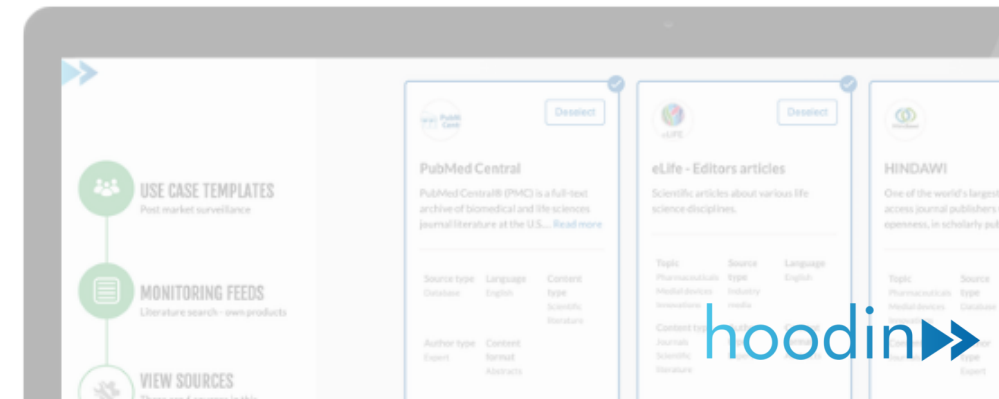Making filing mistakes leading to costly delay

Contributing limited or unreliable information to wider teams

Impacting on your or your team's or company's reputation

Holding you back in your career

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Example: The real cost of not staying current

Project:
Registration of a secondary indication for high revenue pharmaceutical product in several EU markets with a relatively high likelihood of success.

Issue:
During the review and following internal discussions it becomes apparent that recent changes to legislation in at least 2 EU member states shows that a new indication could instigate a pricing review of the marketed product.

Impact:
A pricing review of the marketed product in the 2 large EU markets would negate any potential profit from the secondary indication.

Outcome:
The company determines it is not in its best interests to pursue the secondary indication and subsequently withdraws it.

Learnings:
Failing to be aware of recent legislation changes can lead to an ineffective regulatory and filing strategy, leading to potential benefits to patients and profits to the company being lost.
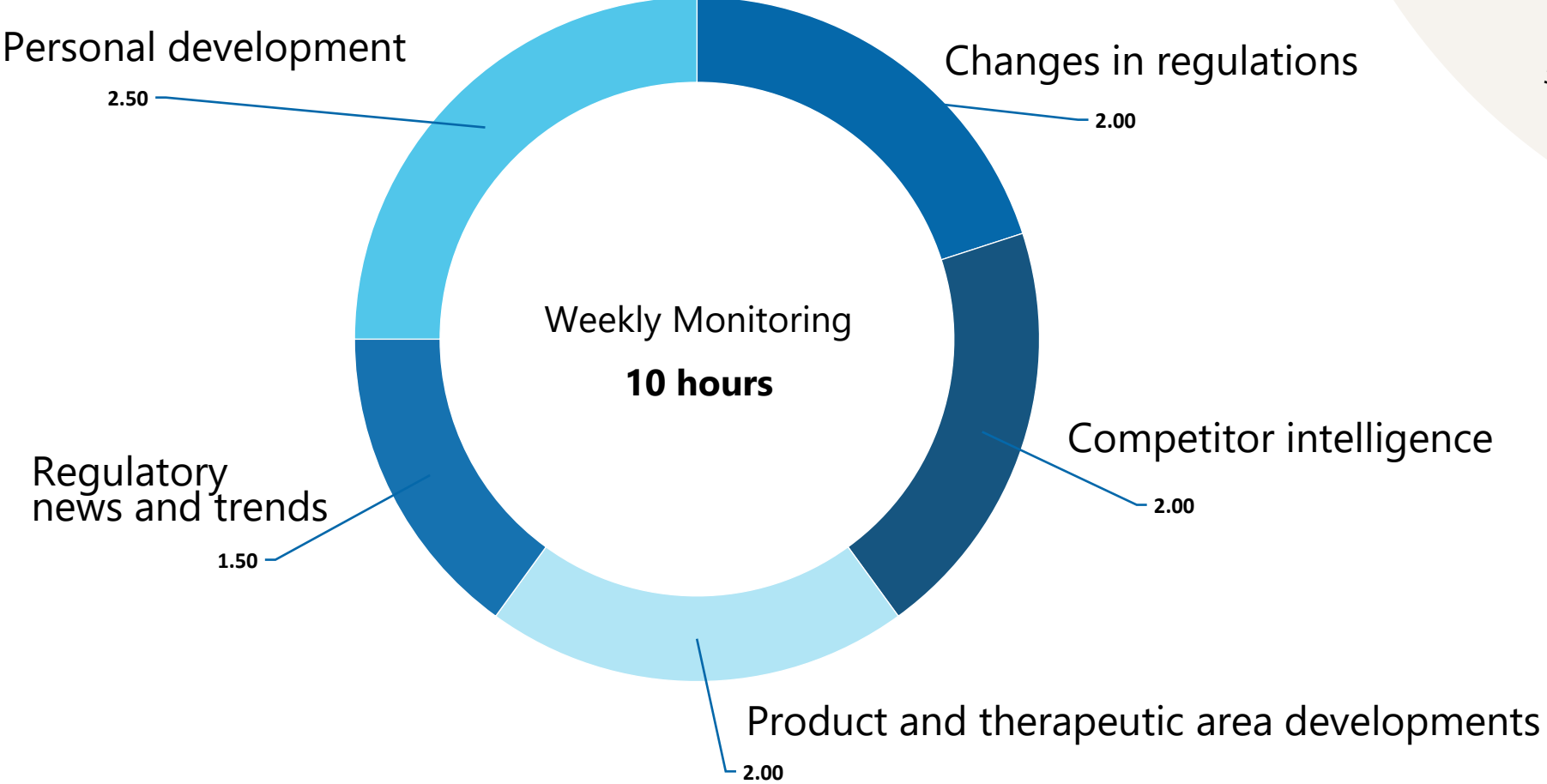
Automated content monitoring and dissemination of findings internally may allow for a more effective strategy to be devised and avoided unnecessary costs and loss of potential revenue.

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Time spent on manual content monitoring?

Small pharma company (5 regulatory personnel) with 10 products launched in the EU

50 weeks per year = 500 hours per year

This equates to approximately
13 working weeks
(38 hours per week)

Personal development
2.50

Changes in regulations
2.00

Weekly Monitoring
10 hours

Competitor intelligence
2.00

Regulatory news and trends
1.50

Product and therapeutic area developments
2.00

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Welcome to automation

The ever-increasing role of automation in our lives

Society
Cars/travel (Tesla cars auto-pilot)
Shopping (Apple pay)
At home (Alexa, Doorbells, vacuum cleaners, coffee makers)

Work
General:
Business intelligence; Finance; Project management
Regulatory:
Text comparison tools; dossier submissions; validation processes

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Automation of Content Monitoring
Semi-automation

Achievable using existing tools, such as:
Google Alerts | Email subscriptions | Newsletters | RSS feeds

Pros
Free to use
Some time saving over manual content monitoring

Cons
Large number of sources need to be located.
Considerable number of results to be filtered/reviewed from various locations.
Collation and dissemination of results is not in one place or straightforward.
Resource intensive.

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Automation of Content Monitoring

Full automation

Platforms, such as Hoodin enable user to carry out monitoring projects all in one place.

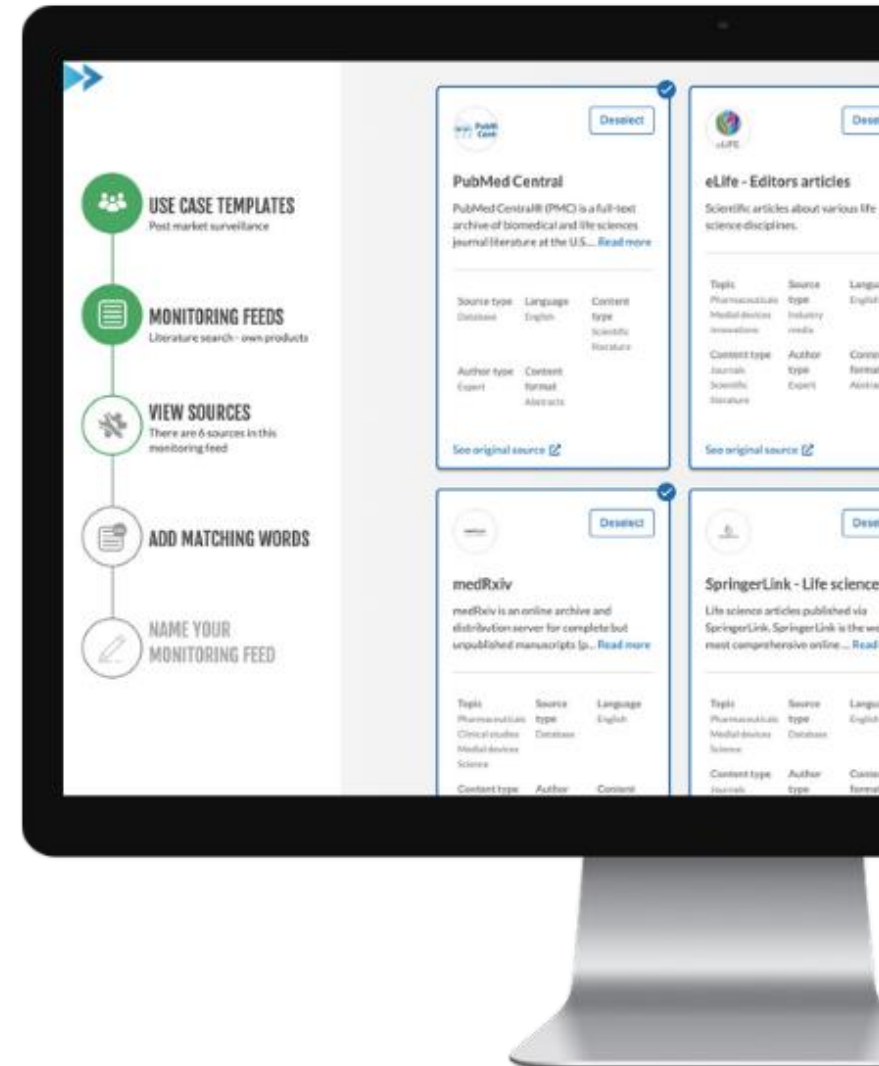**Pros**
Majority of sources pre-determined
Results all in one place
Sharing and commenting of results from within platform
Repeated searches not required
Reports can be produced and shared from within platform
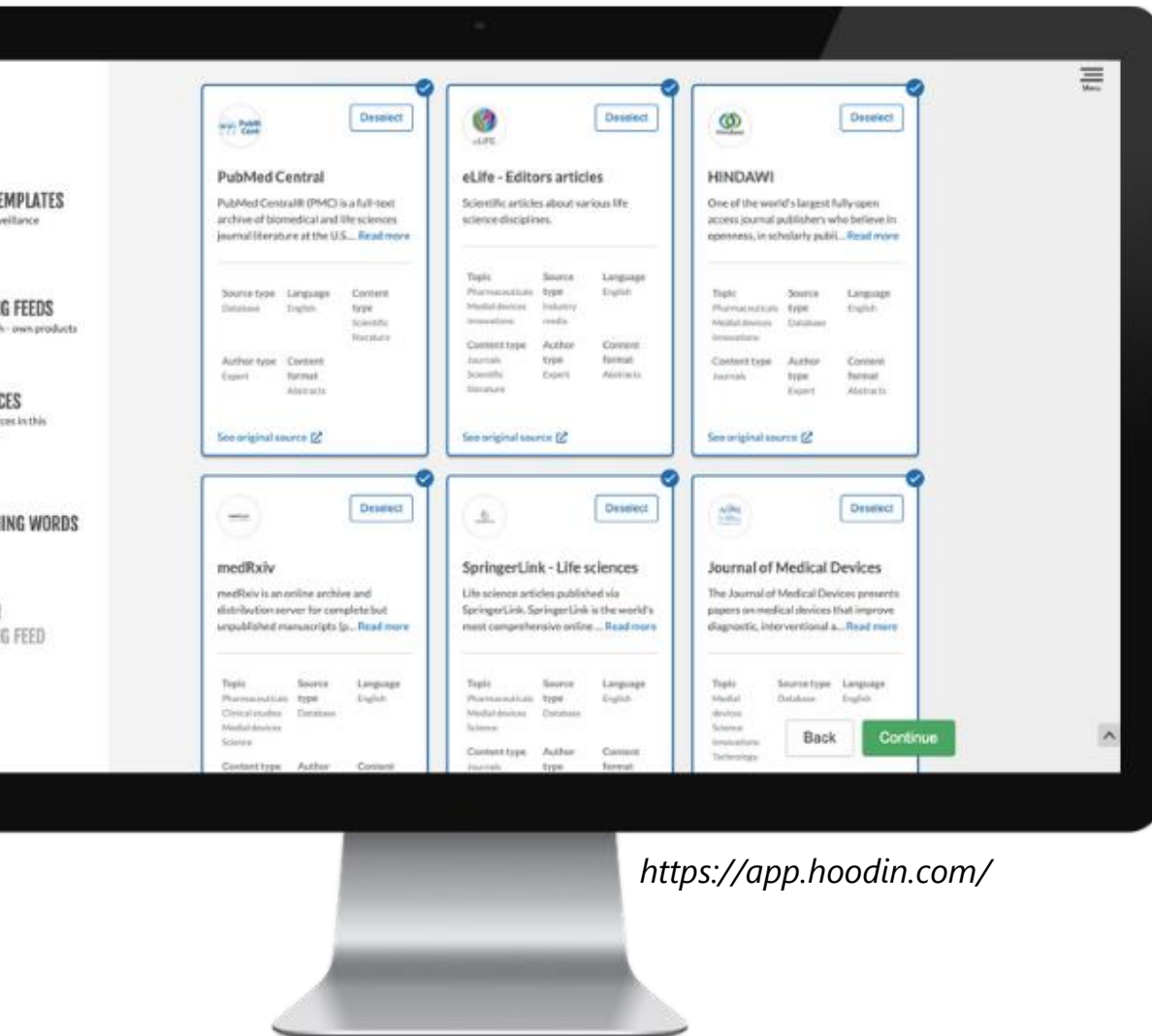Large time saving over manual and semi-automated content monitoring

Cons
Cost involved
Some training required

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Demo: Automated Content Monitoring

https://app.hoodin.com/

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Summary

Changing Regulatory Landscape

- Regulations and policies continue to grow and staying current becomes ever more important

- Mitigating against regulatory risk is a vital part of any solid regulatory strategy

Automation

- Tools for automating processes and tasks are growing in number and utilising them is essential to increasing efficiency

- Dedicating resource to finding and understanding new and existing automation is time and money well spent

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Questions and Answers

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Thank you!

| nicholas@hoodin.com

| marcus@hoodin.com

| www.hoodin.com

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