

PMS Automation with AI:

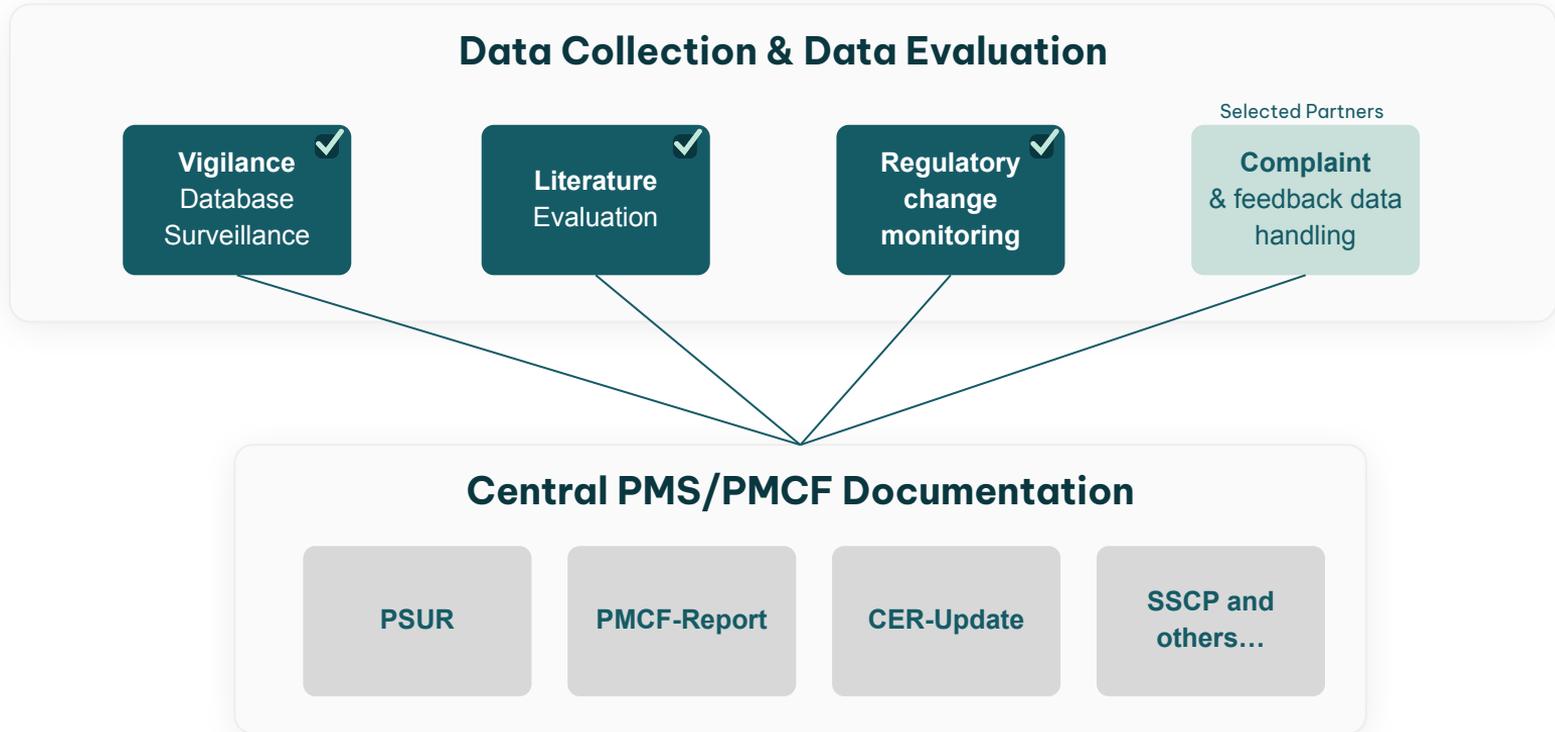
Potentials and challenges in applying AI in
MedTech



Flinn is the leading partner for AI in MedTech Compliance.



Flinn Areas of Activity



FLINN

Literature Evaluation



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Opportunities of AI in Literature Evaluation



Example 1

Generate Efficiency

Searches / Results /

Klein, 2013, Science Direct

✓ Purchased ✗ Published: 31/05/2013 [10.1093/eurheartj/eh167](#)

Subcutaneous Implantable Cardioverter Defibrillator: A Contemporary Overview

Helmut U. Klein | Ilan Goldenberg | Vincent van Dijk | Hans Römers | Mike Smart | + 6 more

Abstract Full text PDF

The difference between subcutaneous implantable cardioverter defibrillators (S-ICDs) and transvenous ICDs (TV-ICDs) concerns a whole extra thoracic implantation, including a defibrillator coil and pulse generator, without endovascular components. The improved safety profile has allowed the S-ICD to be rapidly taken up, especially among younger patients. Reports of its role in different cardiac diseases at high risk of SCD such as hypertrophic and arrhythmic cardiomyopathies, as well as channelopathies, is increasing. S-ICDs show comparable efficacy, reliability, and safety outcomes compared to TV-ICD. However, some technical issues (i.e., the inability to perform anti-bradycardia pacing) strongly limit the employment of S-ICDs. Therefore, it still remains only an alternative to the traditional ICD thus far. This review aims to provide a contemporary overview of the role of S-ICDs compared to TV-ICDs in clinical practice, including technical aspects regarding device manufacture and implantation techniques. Newer outlooks and future perspectives of S-ICDs are also brought up to date.

Results

Three samples were recruited: a pilot sample of 20; a reduction sample of 152; and a validation sample of 148. The presence of 6 dimensions was confirmed: 1) Loss of sex

Insights Analysis Appraisal Comments



Flinn recommends to **exclude**

Irrelevant study type **Unlikely**

Different device or technology **Likely**

Understandable language **Unlikely**

Irrelevant intended purpose **Likely**

Inappropriate population **N.A.**



Report w

AI supported suggestion to include/exclude

Evaluation ∨

Unrated **Include**

? Possibly included

⊘ Exclude



← 19 of 73 →

Example 2

Increase Compliance & Avoid Non-Conformities

Searches /

Literature, Device Group 1, 2023

Results Included # 220 Create export Config

Flinn found 3 additional papers that are very likely relevant. [Review now](#)

Status	Type	Title	Author(s)	Source	Date ↑
	Journal Article	A stomata-inspired superhydrophobic portable filter system.	Yu...		
	Journal Article, Research...	Altered Cardiac Energetics and Mitochondrial Dysfunction in Hypertrophic Cardiomyopathy.	S...		
	Case Reports, Journal Article,...	Quantitation of sibutramine in human hair using gas chromatography-isotope dilution tandem mass spectrometry.	H...		
	Journal Article	Exploration of the co-structuring and stabilising role of flaxseed gum in whey protein isolate based cryo-hydrogels.	T...		
	Systematic Review	Efficacy and Safety of Pleural Cryobiopsy vs. Forceps Biopsy for Evaluation of Undiagnosed Pleural Effusion: A Systematic Review and...	Mohan Giri, Haiyun Dai, Shuliang Guo,...	Livivo	11.04.22
	Journal Article	Building Biological Relevance Into Integrative Modelling of Macromolecular Assemblies.	Anne-Elisabeth Molza, Yvonne...	Cochrane	11.04.22
	Journal Article	Structural Characterization of the Full-Length Anti-CD20 Antibody Rituximab.	Benny Danilo Belviso, Giuseppe...	PubMed	11.04.22
	Journal Article	Structures of Omicron spike complexes and implications for neutralizing antibody development.	Hangtian Guo, Yan Gao, Tinghan Li,...	GoogleScholar	15.04.22
	Journal Article, Research...	Cryo-EM structures of the $\beta 3$ adrenergic receptor bound to solabegron and isoproterenol.	Ikko Nureki, Kazuhiro...	PubMed	19.04.22
	Journal Article	Unraveling the binding mechanism of the active form of Remdesivir to RdRp of SARS-CoV-2 and designing new potential analogues: Insight...	Muhammad Arba, Nicholas Paradis,...	PubMed	20.04.22

AI-recommendations based on your evaluation to not miss relevant papers your query excludes.

Example 3

Convert Unstructured Data in Structured Data

Reduce Repetitive Tasks

The screenshot shows a research article page with a dark blue callout box containing the text "Automated, structured extraction of relevant information". The page includes a navigation bar with "Back", "Abstract", "Full text", and "PDF" options. The article title is "Quo Vadis, Amadeo Hand Robot? Hand Recovery Predictive Model". The authors are Pedro Amalio Serrano-López Terradas and Teresa Criado Ferrer. The article is published in the International Journal of Environmental Research and Public Health. The abstract describes a bi-phase cross-over prospective study comparing COHT and RAT therapies. The article is available as a PDF. The right sidebar shows a list of entities extracted from the text, including "Number of Patients" (58), "Manufacturers mentioned" (Tyromotion GmbH), "Devices mentioned" (Amadeo), and "Relevance for Marketing Claims" (Strong relevance). The bottom of the page shows a "check for updates" button and a citation for the article.

International Journal of Environmental Research and Public Health

Article
Quo Vadis, Amadeo Hand Robot? Hand Recovery Predictive Model

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Abstract: Background. Early identification of hand-prognosis-factors at patient's admission could help to select optimal synergistic rehabilitation programs based on conventional (COHT) or robot-assisted (RAT) therapies. Methods. In this bi-phase cross-over prospective study, 88 stroke patients were enrolled in two randomized groups. Both groups received same treatments A + B (A = 36 COHT sessions for 10 weeks; B = 36 RAT sessions for 10 weeks; 45 min/session; 3 to 5 times per week). Outcome repeated measures by blinded assessors included FMUL, BBT, NHPT, Amadeo Robot (AHR) and AMPS. Statistical comparisons by Pearson's rank correlations and one-way analyses of variance (ANOVA) with Bonferroni posthoc tests, with size effects and statistic power, were reported. Multiple backward linear regression models were used to predict the variability of sensorimotor and functional outcomes. Results. Isolated COHT or RAT treatments improved hand function at 3 months. While "higher hand paresis at admission" affected to sensorimotor and functional outcomes, "laterality of injury" did not seem to affect the recovery of the hand. Kinetic-kinematic parameters of robot allowed creating a predictive model of hand recovery at 3 and 6 months from 1st session. Conclusions. Hand impairment is an important factor in define sensorimotor and functional outcomes, but not lesion laterality, to predict hand recovery.

Keywords: Amadeo®; hand; occupational therapy; rehabilitation; robotics; stroke

1. Introduction

Improving hand hemiparesis of the upper limb (UL) and its functional impact after stroke remains the main objective in neurorehabilitation. At four years after the stroke, only 4% of patients are satisfied with the functionality achieved, considering chronic deficit in almost 50% of cases [1]. Location, extension and severity of the neurological lesion, more frequent in the middle or anterior cerebral arteries, entail heterogeneity of sensorimotor, cognitive, emotional and functional signs and symptoms that condition different types of neurological hand syndromes, determining the degree of disability of the person and their subsequent level of autonomy achieved in everyday life. Atypical clinical pictures of anosognosia, somatoparaphrenia or alien hand can occur after acquired brain damage (ABI), in addition to the more typical hand syndromes of apraxia or neglect. In the early stages of recovery, a better prognostic factor is an initial capacity for distal activation of the hand in one or more fingers and a lower presence of sensitivity impairment [1,2]. The presence of a greater degree of motor and somatosensory involvement in the UL at the beginning of the intervention, as well as the location and lateralization of the injury, could

Number of Patients
58

Manufacturers mentioned
Tyromotion GmbH

Devices mentioned
Amadeo

Relevance for Marketing Claims
Strong relevance

Evaluation
Unrated Include
Possibly included Exclude

19 of 73

check for updates

Citation: Serrano-López Terradas, P.A.; Criado Ferrer, T.; Jakob, I.; Calvo-Arenillas, J.I. Quo Vadis, Amadeo Hand Robot? A Randomized Study with a Hand Recovery Predictive Model in Subacute Stroke. *Int. J. Environ. Res. Public Health* **2023**, *20*, 690. <https://doi.org/10.3390/ijerph20010690>

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Example 4

Increased Consistency

Searches / Results /

IM HIS13402

Automated, AI-based detection of very similar and duplicated results.

Type of Device **Brand Name** **Product Code**

DEFIBRILLATOR/ PACEMAKER	GALLANT DR	NIK
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[Show more](#)

Event Type **Event Date** **Report Date**

Death	12/07/2022	11/09/2022
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Device Problem **Patient Problem** **Adverse Event Report**

Failure to Convert Rhythm (1540); Under-Sensing (1661)	Arrhythmia (1721)	Yes
---	-------------------	-----

Event Description VI

The patient was experiencing ventricular fibrillation (vf) in a non-clinical environment. The device diagnosed the vf and delivered therapy; however the vf signal had a low amplitude which the device then undersensed.

Insights Data Comments History

Flinn Assistant

Flinn found 2 equivalent results with the IDs:

- 123456789
- 987654321

Evaluation

Unrated Include Possibly included Exclude

- Relevant device
- Relevant application
- Relevant patient group
- Data/report quality

Appraisal notes

Cancel Approve < >

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Challenges of AI in MedTech



Some challenges you should be aware of using AI in MedTech



Data Privacy

Ensure Confidentiality:

Select the right safety measures to prevent unauthorized sharing or exposure.



Model Performance & Hallucination

Achieve Model Reliability:

Use fine-tuned models for each specific use case instead of a standard model for all.



Validation

Choose Optimal Validation:

Select the approach that best fits each specific application to achieve reliable & compliant outcomes.

Validation of AI

Example 1 - Gold Standard Validation: Extraction of specific Data (e.g., device used in study)



There is a clear answer to the question, thus a 100% accurate test-set can be derived.



A performance threshold is set for the validation, e.g., 99% accuracy.



AI evaluated results are compared to the correct test set; only if there is a match it counts.

The screenshot shows a research article titled "Quo Vadis, Amadeo Hand Robot? A Randomized Study with a Hand Recovery Predictive Model in Subacute Stroke" from the International Journal of Environmental Research and Public Health. The article authors are Pedro Amalio Serrano-López Terradas, Teresa Criado Ferrer, Iris Jakob, and Jose Ignacio Calvo-Arenillas. The article discusses a phase cross-over prospective study comparing conventional (CCHT) and robot-assisted (RAT) therapies for stroke patients. The abstract mentions that isolated CCHT or RAT treatments improved hand function at 3 months, with RAT showing significantly better results. The article also includes a predictive model for hand recovery based on sensorimotor and functional outcomes.

On the right side of the screenshot, there is a sidebar with AI extraction results:

- Number of Patients:** 58
- Manufacturers mentioned:** Tyromotion GmbH
- Devices mentioned:** Amadeo
- Relevance for Marketing Claims:** Strong relevance
- Evaluation:** Unrated, Include, Possibly included, Exclude

At the bottom of the sidebar, it indicates "19 of 73" items.

Validation of AI

Example 2 - Majority Vote Consensus Validation: Categorizing a device problem according to IMDRF code

Very complex question, not one exact truth: Multiple codes may apply simultaneously, as there's no single "correct" answer.

The formulation of the validation threshold is different: e.g., the goal is for the model's classification accuracy to match the level of human experts.

Both the AI model and an expert user group classify the same dataset. An independent board reviews the results and makes a majority vote for each case, without knowing the source of each answer.

The validation succeeds if the AI model performs as accurately as the human expert group in the majority of cases.



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Your Specialist for AI in MedTech Compliance.



Trusted by some of the largest MedTech manufacturers worldwide, as well as numerous regional champions, like:

