

The impact of **NLP technology** on clinical regulatory activities



André Dias
CCO

 **Giotto Compliance**

Giotto.ai i n a nutshell



Company

Swiss company established in 2017
on the prestigious campus of the
Swiss Federal Institute of
Technology Lausanne



Giotto Compliance

The first web application to
automate and digitalize the clinical
evaluation of medical devices



Technology

Focus on enhancing
interpretability and robustness of
AI thanks to geometry

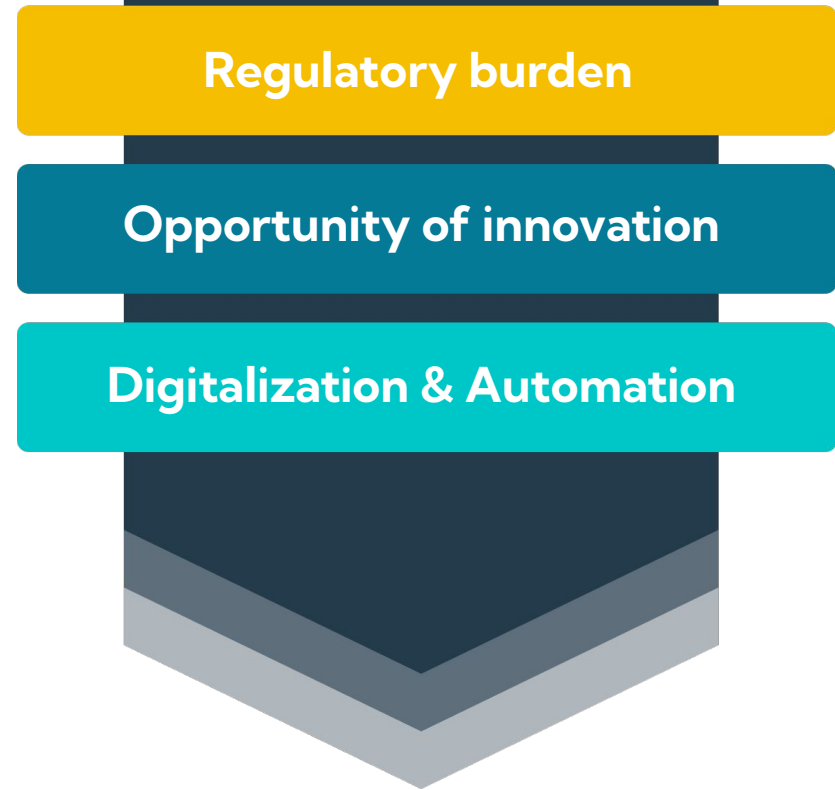


Team

35 employees, award-winning
founding team supported by seasoned
managers and entrepreneurs



The Bright Side of the EUMDR



Faster Submissions, approvals, and updates



Increased speed to market



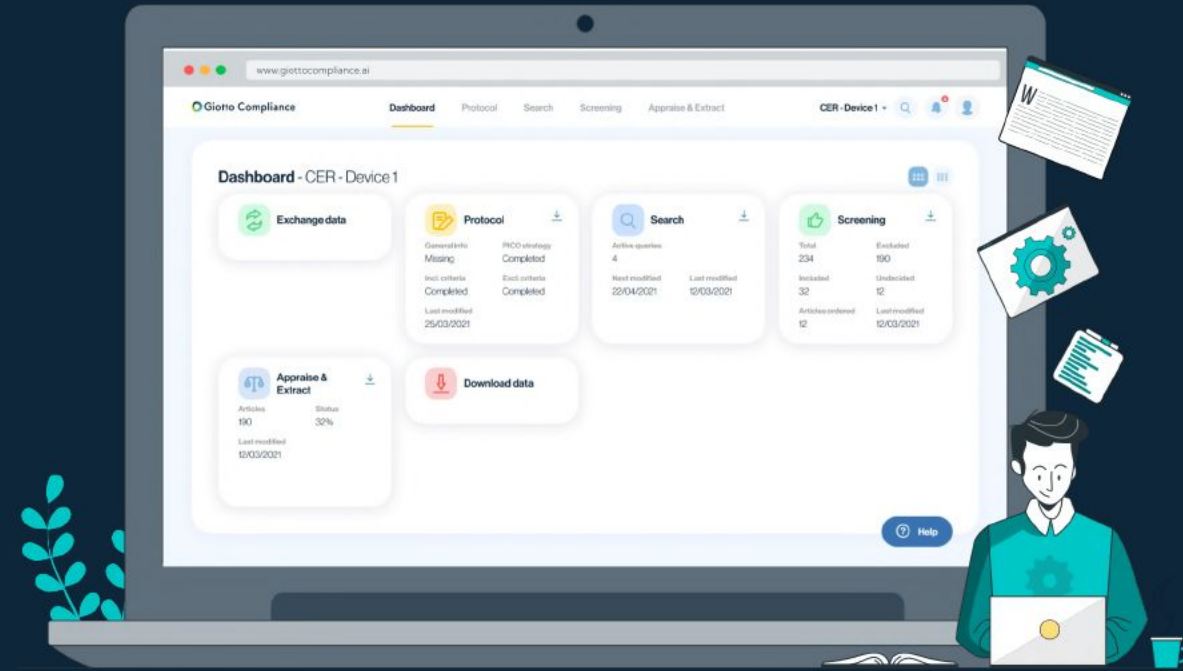
Greater overall competitive advantage

Our solution - Overview

Giotto Compliance is an **all-in-one platform** to automate, digitalize, and standardize the data collection, analysis and writing of **Clinical Evaluation Reports (CERs)**.

Overall, our customers (MedTech companies worldwide) are happily using Giotto Compliance to save an impressive amount of time and to **move into a very digitalized and organized CER workflow with a strong automation component.**

 Giotto Compliance



Using NLP technology to streamline the screening of references

(based on title

Giotto Compliance Dashboard Protocol Search **Screening** Appraise & Extract Demo project

Screening - review mode < Back | List view [Menu] [Add] [Settings] [Download]

Giotto recommends excluding this reference for R4 with 50% confidence.

Prev. reference 4 of 92 Next reference 6 of 92

Adhesion of resin composite to h...
Authors: Saracoglu, A, Ozcan, M, Kumbuloglu, O, Turkun, M
Included (R1)

Povidone-iodine 1% is the most effective vaginal antiseptic for preventing post-cesarean endometritis: a systematic review and network meta-analysis.
Authors: Roeckner, Jared T, Sanchez-Ramos, Luis, Mitta, Melanie, Kovacs, Andrew, Kaunitz, Andrew M
Journal: Am J Obstet Gynecol
Abstract: BACKGROUND: Direct comparison metaanalyses have reported benefits with presurgical vaginal preparation before cesarean delivery for the reduction of endometritis. These reports did not perform a multitreatment comparison of the various antiseptic solutions assessed in previous studies. OBJECTIVE: The purpose of this study was to review the literature systematically and quantitate and summarize indirectly the comparative efficacy of antiseptic for...
Undecided

Oral hygiene care for critically...
Authors: Zhao, Tingting, Wu, Xinyu, Zhang, Qi, Li, Chunjie, ...
Included (R1)

Excluded: 16
Included: 6
Undecided: 70
Update ranking
Automate

Exclude [?] Include

Help

Using NLP technology to streamline Data Extraction

(from full text publications)

Appraise & Extract - review mode

Name	Answer 1	Answer 2	Answer 3	Manual
Appropriate device Were the data generated from the device in question?	<input type="radio"/> D1 - Actual device	<input type="radio"/> D2 - Equivalent device	<input type="radio"/> D3 - Benchmark devices, Alternative treatment options	<input type="checkbox"/> N/A <input type="checkbox"/>
Appropriate device application Was the device used for the same intended use (e.g., methods of deployment, application, etc.)?	<input type="radio"/> A1 - Same use	<input type="radio"/> A2 - Minor deviation	<input type="radio"/> A3 - Major deviation	<input type="checkbox"/> N/A <input type="checkbox"/>
Appropriate patient group Were the data generated from a patient group that is representative of the intended treatment population (e.g., age, sex, etc.) and clinical condition (i.e., disease, including state and severity)?	<input type="radio"/> P1 - Applicable	<input type="radio"/> P2 - Limited	<input type="radio"/> P3 - Different population	<input type="checkbox"/> N/A <input type="checkbox"/>
Acceptable report / data collation Do the reports or collations of data contain sufficient information to be able to undertake a rational and objective assessment?	<input type="radio"/> R1 - High quality	<input type="radio"/> R2 - Minor deficiencies	<input type="radio"/> R3 - Insufficient information	<input type="checkbox"/> N/A <input type="checkbox"/>
Data source type Was the design of the study appropriate?	<input type="radio"/> T1 - Yes	<input type="radio"/> T2 - No		<input type="checkbox"/> N/A <input type="checkbox"/>
Outcome measures Do the outcome measures reported reflect the intended performance and safety of the device?	<input type="radio"/> O1 - Yes	<input type="radio"/> O2 - Yes, partially	<input type="radio"/> O3 - No	<input type="checkbox"/> N/A <input type="checkbox"/>
Follow up	<input type="radio"/> F1 - Yes	<input type="radio"/> F2 - Yes.	<input type="radio"/> F3 - No	<input type="checkbox"/> N/A <input type="checkbox"/>

Data appraisal **Data extraction**

Treatment of scaphoid waist fractures with the HCS screw
Research Article

Abstract

The aim of the study was to evaluate the clinical results of the Headless Compression Screw (HCS, Synthes) when used for treatment of acute scaphoid waist fractures. The new screw design generates interfragmentary compression with use of a compression sleeve. Twenty-one patients were treated for acute scaphoid waist fractures type B2 with HCS screws. The average time to the final follow-up examination was 12.8 months. All 21 fractures united after a mean time of 7.2 weeks. The mean DASH score was 7.1. The average motion of the wrist in extension was 61°, flexion was 46°, radial abduction reached 25° and the ulnar abduction was 31°. The maximally achieved grip strength was 86% compared to the uninjured side. Treatment of type B2 scaphoid fractures with the Headless Compression Screw showed good functional and radiographic results. The results are similar to those identified using other screw fixation systems.

Keywords: scaphoid fracture, screw fixation, percutaneous fixation, HCS screw

Zusammenfassung

Die Headless Compression Screw (HCS, Synthes) ist eine Weiterentwicklung der Herbert-Whipple-Schraube und kann zur perkutanen Behandlung von Skaphoidfrakturen eingesetzt werden. Das modifizierte Schraubendesign soll den interfragmentären Druck durch Anwendung einer Kompressionshülse erhöhen. In dieser Studie wurden die klinischen und radiologischen Ergebnisse nach Schraubenosteosynthese durch die HCS bei Skaphoidfrakturen des mittleren Drittels analysiert. In die retrospektiven Studie wurden 21 Patienten nach HCS-Schraubenosteosynthese bei akuter Skaphoidfraktur (Typ B2 n. Herbert) aufgenommen. Die Nachuntersuchung wurde nach 12,8 Monaten durchgeführt.

Alle 21 Skaphoidfrakturen heilten knöchern nach durchschnittlich 7,2 Wochen aus. Der mittlere DASH Score betrug 7,1 Punkte, die Handgelenkbeweglichkeit in Extension 61°, in Flexion 46°, in Radialabduktion 25° und in Ulnarabduktion 31°. Die Griffkraft lag bei 86% im Vergleich zur gesunden Gegenseite. Die Behandlung der Skaphoidfraktur des mittleren Drittels mit der HCS-Schraube führte zu guten funktionellen und radiologischen Ergebnissen, die vergleichbar sind mit denen ähnlicher Schraubensysteme.

Schlüsselwörter: Skaphoidfraktur, Schraubenfixierung, perkutane Fixierung, HCS-Schraube

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Help

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Performance of NLP applied to screening and data

Title + Abstract screening

- ✓ Sensitivity: **83%**
- ✓ Negative predictive value: **93%**

Screening - review mode

Giotto recommends excluding this reference for RS with 90% confidence.

The effect of sodium hypochlorite enamel pretreatment on the shear bond strength of fissure sealant using a resin-modified glass ionomer cement and a fluoride-releasing self-etch resin adhesive.

Authors: Najmeh Mohammadi; Ali Karinkhani; Rafat Bagheri; David J Manton

Journal: Dent Res J (Isfahan)

Abstract: BACKGROUND: The relative high caries risk of pits and fissures highlights the importance of protecting these areas. The aim is to determine the effect of sodium hypochlorite (NaOCl) on the shear bond strength (SBS) of resin-based pit and fissure sealant (RPFSS) material to enamel using resin-modified glass ionomer cement (RMGIC) and fluoride-releasing self-etch resin (FRSE) adhesives. MATERIALS AND METHODS: In this in vitro study extracted third...

Excluded: 3
Included: 3
Undecided: 51
Update ranking
Automate

Exclude Include

Full-text data extraction

- ✓ Total accuracy: **83.3%**
- ✓ Accuracy for value-set questions: **93.6%**
- ✓ Accuracy for numerical questions: **76.3%**

Appraise & Extract - review mode

Name	Answer 1	Answer 2	Answer 3	Manual
Study type	Randomized controlled trial			
No. of study arms	2			
Dataset ID 1	Sodium Fluoride Varnish (NaFV) Group			
No. of patients - enrolled	154			
No. of patients - completed	133			
No. of teeth - enrolled	567			
No. of teeth - completed	475	Click to visualize the answer on the PDF.		
Indication	Caries prevention			
Products - device	sodium fluoride varnish			
Males	76			
Females	78			
Age - mean				
Age - SD				
Age - min	3			
Age - max	4			
Complication ID 1				
Continuous endpoint ID 1	ICDAS 0-1 (Baseline)			

Mark all as NA Approve all Unapprove all

Research Article

Glass Ionomer Sealant versus Fluoride Varnish Application to Prevent Occlusal Caries in Primary Second Molars among Preschool Children: A Randomized Controlled Trial

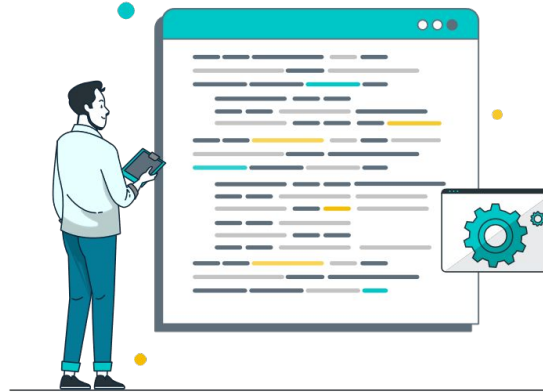
Phoebe Pui Ying Lam¹, Divesh Sardana², Weijia Luo³, Manikandan Srambam⁴, Gillian Hiu Man Lee⁵, Edward Chin Man Lo⁶, Cynthia Kai Yung Yiu⁷

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Keywords: Pits and fissure sealants; Fluoride varnish; Caries prevention; Preschool children; Randomized controlled trial

Abstract: Fissure sealant is a recommended preventive measure on permanent molars, but its efficacy on primary molars in preschool children is still in doubt. Sodium fluoride varnish (NaFV) enhances remineralization and is effective in preventing caries in smooth surfaces, but limited information is available regarding its use on occlusal surfaces of primary

Key Take Aways



✓ NLP technology can effectively support humans on time-consuming regulatory activities.

✓ The natural evolution of the regulations will catalyze the adoption of regulatory intelligence tools powered by AI.