



## Academic-industry partnership advancing cannabis science: A Complementary Care Practice-Based Research Network

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### ABSTRACT

**Objectives:** Data collected during routine care holds the potential to support hypothesis generation, study feasibility, and provide insight regarding how to address problems under real world conditions. Currently there are no practice-based research networks in Florida that focus on complementary care in general or medical marijuana specifically. Through an academic-industry partnership, we sought to develop a practice-based research network focused on cannabis science and create a de-identified database for analyses that support hypothesis generation, study feasibility estimation, and a network that also facilitates recruitment into future research studies.

**Design:** The Complementary Care Practice-Based Research Network (CC-PBRN) is a centralized repository, which contains electronic health records (EHR) from a private medical cannabis health system in the state of Florida. **Results:** This paper provides cross-sectional descriptive analyses of the CC-PBRN's 43,802 currently active patients. There are 24 clinics in the network with nine in North Florida, 11 in Central Florida, and 4 in South Florida.

**Conclusion:** This network serves as a statewide resource for patient-reported outcomes (PRO) research in medical marijuana. The network currently has numerous outpatient practices with thousands of patients that are a potential source of research participants for both observational studies as well as traditional clinical trials. The outpatient clinical practices can also serve as units of analysis for pragmatic trials comparing different care protocols and organizational structure.

### 1. Introduction

Across all sectors of industry, vast amounts of data regarding health and health outcomes are collected on a routine basis.<sup>1</sup> Data collected during routine care holds the potential to support hypothesis generation, study feasibility, and provide insight regarding how to address problems under real-world conditions. Therefore, successful academic-industry partnerships, which put unused data from industry to work, have the potential to advance science and have significant public health impact.<sup>1–3</sup> However, there are numerous limitations that prevent the use of data collected by industry for the greater good of scientific innovation.<sup>4</sup> Traditional models of data management require academics to collect their own data, and industry uses the data they collect to advance their business models. Because academic researchers require academic freedom to report the data as they see fit whether or not it aligns with the

business model, the traditional model of collaboration with academics in the era of big data often fails.<sup>1</sup>

Currently there are no practice-based research networks in Florida that focus on complementary care in general or medical marijuana specifically. Practice-based research networks started in the 1970s to provide data on primary care health concerns.<sup>5</sup> Today, these networks have developed and serve multiple functions, such as focusing on patient-oriented outcomes, improving delivery and quality of care, practice-based transformation model, community health improvement, and patient engagement.<sup>6–9</sup> Through an academic-industry partnership, we sought to develop a practice-based research network focused on cannabis science to create a de-identified database for analyses that support hypothesis generation, study feasibility estimation, and a network that also facilitates recruitment into future research studies. The aims of this paper are to: (1) describe the process utilized in the

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development of the Complementary Care Practice-Based Research Network (CC-PBRN), (2) present baseline descriptive characteristics of the practice-based research network, and (3) discuss the challenges and lessons learned in initiating an academic-industry partnership.

## 2. Developing the practice based research network

The CC-PBRN is an academic-industry partnership between Florida State University's intervention Research Advancing Care Equity Lab (FSU-iRACE) and Medical Marijuana Treatment Clinics of Florida (MMTC) that serves the advancement of medical cannabis science through patient-reported outcomes. In order to ensure a successful partnership, FSU-iRACE and MMTC first met to identify the challenges a partnership could create and to develop solutions that worked with the culture of both organizations. The three Cs of collaboration, coordination, and cooperation, a traditional method of partnership building in interorganizational relationships,<sup>10</sup> was used as the framework to develop a resilient academic-industry partnership. A combination of in-person and virtual platform meetings allowed for more frequent meetings and supported the development of the partnership, which started July 2020. The first several meetings consisted of collaboration building, which involved the teams from each organization getting to know the organizational structure of their potential partner in a more detailed-oriented manner,<sup>10-12</sup> specifically how each organization worked independently and the purpose collaboration would serve for each organization. By the third meeting, a strengths, weaknesses, opportunities, and threats (SWOT) analysis was completed in order to understand the resources that were available within each organization.<sup>13,14</sup> The SWOT then served as the foundation for why the organizations should collaborate and enabled operationalization of a mission for the collaborative partnership.

The next major step was coordination, which required a review of operations on both sides.<sup>15,16</sup> It was integral for FSU-iRACE researchers to understand what data was collected, how it was collected, how it is stored, and how it is governed. It was equally as important for MMTC to understand what data management and computing resources, research expertise, data analysis capabilities, and grant writing skills FSU-iRACE researchers currently had available to devote to the project. Once the mechanics of operations were understood, FSU-iRACE researchers drafted a concrete plan with actionable items that were assigned to each organization. That plan was sent to MMTC for review and approval. After MMTC approved the plan, negotiations for how to implement that plan moved beyond the FSU-iRACE researchers and MMTC business owners. A formal data use agreement and a business associate agreement were identified as the primary and appropriate governing structures for this partnership. At this stage of cooperation, both FSU-iRACE and MMTC referred the draft collaboration plan to their institutional legal teams for review.<sup>15,17-19</sup> Institutional review on both sides entailed several revisions and negotiations, which ultimately led to the development of a formal data use agreement that governs the CC-PBRN. It is important to note that this is an iterative process requiring open and clear communication from each side. Therefore, after translating the data use agreement into actionable steps, it is revisited regularly by repeating steps one through three in interorganizational team meetings.

## 3. Methods

### 3.1. CC-PBRN structure

The CC-PBRN is a centralized repository, which contains de-identified electronic health records (EHR) from the MMTC health system, a private medical cannabis health system in the state of Florida. FSU-iRACE and MMTC signed data use agreements, which allowed for the transfer of EHR Health Insurance Portability and Accountability Act-limited data sets to the data trust repository. Data elements from the EHR include diagnoses, procedures, place of service, vital signs, and

patient-reported outcomes. The CC-PBRN data team has considerable experience with data standards and Logical Observation Identifiers Names and Codes (LOINC), which are used to ensure that the data are well-organized for research purposes. Data was downloaded from the MMTC electronic medical record July 2021 and final analyses of that data reported here were completed November 2021. All currently active patients (N = 43,802) with a certified qualifying medical condition were included in analyses. The CC-PBRN data protocol is approved by the Florida State University Institutional Review Board (FSU IRB).

FL Medical Marijuana Laws: Qualifying Medical Conditions and the Process of Certification.

To be certified for medical marijuana in the state of Florida patients must schedule an appointment with a qualified medical marijuana physician to receive certification of eligibility for a medical marijuana card. In Florida patients must pay for a physician to certify them which is approximately \$150-\$200 depending on the physician. This cost is not covered by any insurance. Once the patient receives certification from a qualified physician they must use the state portal to apply online for their medical marijuana use registry identification card. Patients also have to pay the state \$75, a license fee, to obtain the card. This fee must be paid to the state yearly.

Patients can only be certified under one diagnosis at a time in Florida. Therefore, while other qualifying conditions can be noted in a patient's chart, physicians must clearly document which one specific qualifying condition they are certifying the patient under. Patients must be certified by a medical marijuana physician every 210 days in order to be an active medical marijuana patient. The state of Florida has a limited number of conditions for which an individual can be certified to obtain a medical marijuana card. Only those diagnosed by a medical doctor with one of the following conditions: (a) Cancer; (b) Epilepsy; (c) Glaucoma; (d) Positive status for human immunodeficiency virus; (e) Acquired immune deficiency syndrome; (f) Posttraumatic stress disorder; (g) Amyotrophic lateral sclerosis; (h) Crohn's disease; (i) Parkinson's disease; (j) Multiple sclerosis can be certified to use medical marijuana in the state of Florida. It is important to note that in the state of Florida only medical doctors who have obtained an additional qualifying license with the state of Florida to certify patients for medical marijuana can do so. Therefore, patients who have been diagnosed by their treating physicians must take their medical records to a qualified medical marijuana physician that has the license to certify them for medical marijuana. When a patient does not have one of the conditions listed above, for example they have sickle cell or lupus or anxiety, or any other condition not on the list, if their symptoms are severe enough and can be marked as comparable to one of the conditions on the list then they can be diagnosed under what is called: (k) Medical conditions of the same kind or class as or comparable to those enumerated in paragraphs (a)-(j).

Beyond categories a-k there are two additional unique categories in the state of Florida noted in the law as (l) and (m) that qualify for certification. For category (l), advocates for those with a terminal condition requested their own category for certification so we now have category (l) A terminal condition diagnosed by a physician other than the qualified physician issuing the physician certification. Condition (m) "Chronic nonmalignant pain" is the most confusing condition in Florida law due to the very narrow definition of the condition. Per Florida law "Chronic nonmalignant pain" means "pain that is caused by a qualifying medical condition or that originates from a qualifying medical condition and persists beyond the usual course of that qualifying medical condition." An example of who fits in that condition is someone who has been cured of cancer and they can no longer be certified under a cancer diagnosis. The law now allows for them to be certified under "Chronic nonmalignant pain" because even though they were originally certified due to having cancer once they are cured, the malignant cancer is gone, if pain still exists possibly from treatment in anyway the patient will still qualify for a medical marijuana card under the chronic nonmalignant pain condition now that they are cancer free. Therefore, if someone did not have any of the diagnoses of a-j and recovered from the diagnosis

then they cannot be certified under condition (m). See Florida Medical Marijuana state statute 381.896 subsection 2 for a more detailed explanation of how Florida defines qualifying medical conditions.

#### 4. Definition of relevant variables

Other Qualifying Conditions: (a) Cancer; (b) Epilepsy; (c) Glaucoma; (d) Positive status for human immunodeficiency virus; (e) Acquired immune deficiency syndrome; (f) Posttraumatic stress disorder; (g) Amyotrophic lateral sclerosis; (h) Crohn's disease; (i) Parkinson's disease; (j) Multiple sclerosis.

Comparable Condition: Medical conditions of the same kind or class as or comparable to those enumerated in (a)-(j) above.

Symptom Reduction: was assessed using data obtained from the EMR during the follow-up patient visit. We chose this measure because it is captured at each patient visit and was readily available in the EMR. The single item used is not a standard validated measure and it did not ask about specific symptoms such as sleep, pain, or mood. Instead it was a single item global patient reported outcome: Indicate the percent reduction in severity of symptoms since your initial visit by selecting one of the following options: No percent; 10%; 20%; 30%; 40%; 50%; 60%; 70%; 80%; 90%; 100%. We assessed the percentage of decrease or no change in symptomatology patients reported at their first recertification visit. The first recertification visit generally occurs 210 days after their initial certification.

#### 5. Data management

In accordance with the FSU IRB, all data collected from MMTC is de-identified, such that no Protected Health Information (PHI) or identifying information is utilized by end-users. De-identified data is stored in the CC-PBRN database, which is maintained on secure servers managed by Florida State University's College of Medicine Information Technology department. After initial data cleaning and recoding by the data team, a completely de-identified dataset is created to allow researchers to analyze the data. To encourage others to use the data, we created a formal concept system that researchers can use to request a de-identified dataset.

#### 6. Data analysis

All analyses were conducted using SAS Version 9.4 (Cary, NC).<sup>20</sup> Tabulated descriptive statistics were computed to examine sample characteristics, including sociodemographics, history of substance use, qualifying medical conditions, and number of certifications and recertifications. The sample was stratified based on qualifying medical condition. This was done because in Florida patients are certified for one of 13 qualifying medical condition, one of which is a roll-up category named "comparable medical condition." A comparable medical condition is defined as "a medical condition of the same kind or class as or comparable to cancer, epilepsy, glaucoma, HIV, AIDS, posttraumatic stress disorder, ALS, Crohn's disease, Parkinson's disease, or multiple sclerosis." Certifications can also be issued for a terminal condition diagnosed by a physician or chronic non-malignant pain which is narrowly defined as pain that is caused by a qualifying medical condition or that originates from a qualifying medical condition and persists beyond the usual course. We grouped those certified under a comparable medical condition in one group and all other qualifying medical conditions (ALS, cancer, HIV/AIDS, etc) were collapsed into a separate group. Chi-Square or t-test analyses when applicable were used to assess potential differences in sample characteristics. Missing data. All data for this paper were reported as is, including variables with missingness which include race and gender. Missingness is identified in socio-demographic table as unknown.

## 7. Results

The CC-PBRN currently has 43,802 active patients (see Table 1). There are 24 clinics in the network, with nine in North Florida, eleven in Central Florida, and four in South Florida. The majority (73.1%) of patients in the network were certified for a comparable medical condition. Post-traumatic stress disorder (PTSD) was the second most common qualifying medical condition (12%), followed by cancer (8%).

Table 1 shows the summary demographic statistics for the entire sample and by qualifying medical condition. The mean age for the CC-PBRN sample is 51.5 years (SD 16.2). 50.07% are female, and majority 49.07% identify as white, with approximately four percent identifying as Hispanic/Latinx. Forty-three percent of the sample report a history of alcohol use and 21% report a history of tobacco use. 34.7% of the sample had only an initial certification, with 35.6% having 1–2 recertifications and 29.6% with 3 or more recertifications. Of the 28,783 with recertification data, 28% (n = 7998) report an 80% or greater reduction in symptoms (see Fig. 1). Chi-square analyses show that men are less likely to be certified under a comparable condition, and those certified under a comparable condition are more likely to report a history of alcohol use.

## 8. Discussion

CC-PBRN is a practice-based research network in Florida with the overarching goal of uniting researchers, physicians, patients, and stakeholders in Florida to address critical gaps in cannabis science knowledge and other complementary care approaches. This network serves as a statewide resource for patient-reported outcomes research in medical marijuana. The CC-PBRN is an academic-industry partnership between FSU-iRACE and MMTC the partnership provides the infrastructure to do biobehavioral complementary care research across a wide variety of complementary approaches with populations in need of these services. The network currently has numerous outpatient practices with thousands of patients that are a potential source of research participants for both observational studies as well as traditional clinical trials. The outpatient clinical practices can also serve as units of analysis for pragmatic trials comparing different care protocols and organizational structures.

## 9. Challenges identified and addressed

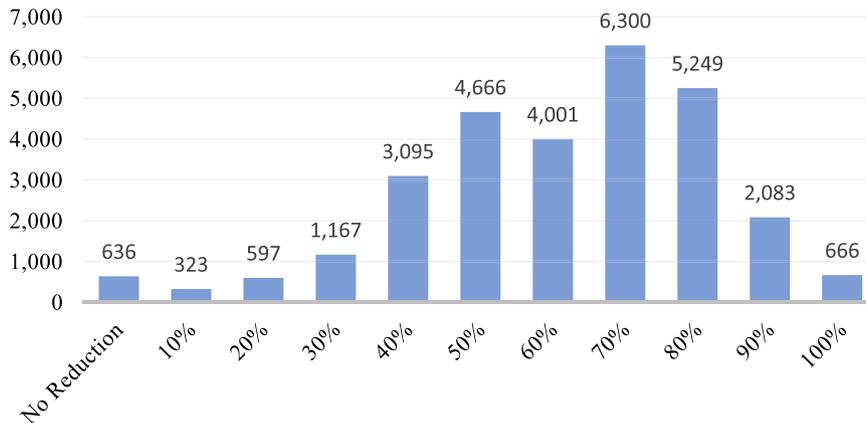
As noted earlier, due to the differing foci of academic and business organizations, there were key challenges that had to be negotiated. The first challenge identified was the concern from MMTC that their proprietary information and process would be publicly disclosed, giving similar businesses a competitive advantage or limit their advantage in the marketplace.<sup>21</sup> To address this we engaged an innovation-focused approach to the research such that the mission of the partnership was to advance complementary care and cannabis science in the state of Florida. The new knowledge would be shared across patient populations, providers, researchers, and policymakers. All knowledge gained benefits both organizations. Further, we work to identify how new knowledge could improve patient care and create new evidence-based practices across the organization. Through this process we developed a working relationship between the organization in which the internal business agenda does not compete with the mission of the CC-PBRN.

The second challenge identified was academic freedom within the research agenda. Researchers on the FSU-iRACE side insisted on academic freedom since often the problems prioritized as most urgent by those in the industry differ from those in academia. It is difficult to find a common issue that both academia and industry have prioritized. Therefore, we identified the resources of the partnership as a way to define clear expertise in certain domains. FSU-iRACE had the academic expertise and skills needed to do the data management and implement

**Table 1**  
Socio-demographics characteristics of the Complementary Care Practice Based Research Network (CC-PBRN).

Sample Characteristics (N = 43,802) <sup>a</sup>								
VARIABLE	ENTIRE SAMPLE		Comparable Condition		Other Qualifying Conditions		TEST STATISTICS	
	M or N	S.D. or %	M or N	S.D. or %	M or N	S.D. or %	$\chi^2$ or t-test	p-value
N	43,802		32,040		11,762			
Age	52.7	16.32	52.1	16.28	54.2	16.35	11.90	< 0.0001
Sex								
Male	21,843	49.87%	15,584	48.64%	6259	53.21%	72.90	< 0.0001
Female	21,931	50.07%	16,440	51.31%	5491	46.68%		
Unknown	28	0.06%	16	0.05%	12	0.10%		
Race								
White	21,494	49.07%	15,607	48.71%	5887	50.05%	21.66	< 0.0001
Black/AA	1552	3.54%	1077	3.36%	475	4.04%		
Other/Unknown	20,756	47.39%	15,356	47.93%	5400	45.91%		
Ethnicity								
Hispanic/Latinx	1649	3.76%	1214	3.79%	435	3.70%	0.84	0.3608
Most Common Qualifying Conditions								
Comparable Condition	32,040	73.15	32,040	100.00%				
PTSD	5269	12.03			5269	44.80%		
Cancer	3526	8.05			3526	29.98%		
Multiple Sclerosis	598	1.37			598	1.37%		
Epilepsy	592	1.35			592	1.35%		
Glaucoma	548	1.25			548	1.25%		
Crohn's	479	1.09			479	1.09%		
Recertification Appointments								
0	15,228	34.77%	11,198	34.95%	4030	34.26%	8.51	< 0.0001
1-2	15,602	35.62%	11,580	36.14%	4022	34.19%		
3+	12,972	29.62%	9262	28.91%	3710	31.54%		
Social History								
History of Tobacco Use	9216	21.04%	6703	20.92%	2513	21.37%	4.74	0.0295
History of Alcohol Use	19,099	43.60%	14,816	46.24%	4283	36.41%	280.38	< 0.0001
History of Marijuana Use	26,322	60.09%	19,412	60.59%	6910	58.75%	0.62	0.43
History of Illicit Drug Use	465	1.06%	312	0.97%	153	1.30%	10.29	0.0013

<sup>a</sup> N may vary slightly according to missing data



N=28,783. Symptom reduction reported at follow-up recertification visit

**Fig. 1.** Symptom reduction reported at recertification visit.

the research plan while MMTC had the data, patients, and providers needed to answer the research questions of interest.<sup>1,22</sup> While there are very few examples of how to negotiate the challenges presented by business-defined priorities versus academic research agendas, reliance on the initial SWOT enabled the partnership to move forward and building of a viable data use agreement.

The third and final challenge was how would we distribute the knowledge outputs generated by the CC-PBRN. Given that business practices generally do not align with the practice of open science, the primary model in academia, we had to identify how business assets would be protected but not interfere with the integrity of the scientific process. In the FSU-iRACE-MMTC collaboration, we had to address that

the knowledge outputs created through the partnership would not have an inherent absolute dollar value return on investment, but instead value added would be how the knowledge could be used to serve the constituents of both organizations. Additionally, the partnership provided an opportunity to advance medical cannabis science, which is limited in the state of Florida,<sup>23,24</sup> and the available expertise to accomplish this task were too important to ignore. We used initial meetings to discuss common practices and expectations around knowledge output dissemination. We identified common intellectual priorities that were independent of business practices, and we created safeguards such as de-identified data, aggregated results, data transformation for scientific purposes, and assurance of academic freedom to ensure

integrity in the process. Ownership of the intellectual property was clearly spelled out in the data use agreement, given that the majority of the research on academic-industry partnerships identify that control and ownership of the intellectual property created through the partnership is often the greatest challenge.<sup>21</sup>

In recent years, the potential efficacy of cannabis as a medical product has generated a great deal of political discourse in the United States and has resulted in pursuits to legalize the use of medical marijuana. Currently 36 states and four territories allow for the medical use of cannabis products. In Florida medical marijuana was approved for use January 2017.<sup>25</sup> The state constitution and Florida statutes specify debilitating conditions eligible for medical marijuana treatment prescribed by a qualified physician – protecting use for cancer, epilepsy, glaucoma, HIV/AIDS, scleroses (ALS and MS), post-traumatic stress disorder, Crohn's disease, Parkinson's disease, and other conditions of similar gravity. However, Florida faces significant gaps in the scientific knowledge needed to manage medical marijuana care due to the limited research that has been conducted in this area<sup>26,27</sup> and specifically the lack of research on patient-reported outcomes (PRO) of use.<sup>23,24</sup> The U. S. Food and Drug Administration defines a PRO as any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else.<sup>28</sup> For optimal results in healthcare, patient input is needed.<sup>29–34</sup> Doctors, researchers, and policymakers need to know what patients feel and perceive about the effects of treatment and services. The CC-PBRN serves as an incubator for PRO research in Florida and throughout the US.

## 10. Strengths and limitations

While the CC-PBRN has numerous strengths, there are several limitations. First, the current EHR system does not force responses for certain demographic data. That data is given voluntarily by patients; therefore, we currently have incomplete demographic data for race, education, and income level. Second, for those certified under a comparable condition, we can only approximate symptoms being treated to the nearest condition allowed by law, which may not reflect all conditions experienced by patients. Third, data regarding other chronic conditions is all self-report, and patients may over-report conditions that have not been diagnosed by a physician. Finally, symptom reduction was not measured using a validated symptom reduction measure. Future work should incorporate validated measures of symptom reduction. Despite these limitations, the CC-PBRN is a vital research network that provides numerous resources for the advancement of complementary care and cannabis science. CC-PBRN is a representative sample of medical marijuana users in the state of Florida<sup>23</sup> and offers investigators the opportunity to engage in research with ethnically, racially, and geographically (rural, urban & suburban) diverse populations across the state of Florida. Research queries can be conducted using de-identified patient records, which assists with hypothesis generation and study feasibility estimations. It also provides support services for implementing grant-funded research in a real-world practice-based setting.

## 11. Conclusion

We described the development of an academic-industry partnership to improve cannabis science, presented descriptive data on the research network, and described the challenges of developing an effective academic-industry partnership. The results of this work demonstrate that academic-industry partnerships that serve the common good are possible with collaboration, communication, and cooperation of all organizations involved. The CC-PBRN is poised as the catalyst for medical marijuana research in the state of Florida. Given the diversity of the populations and chronic conditions in the network, it will also support patient reported outcomes research across a host of complementary care approaches. The data generated by the CC-PBRN can be used to inform

and guide patient-centered care, clinical decision-making, and health policy decisions. These data are an important component in learning healthcare systems. Sawatzky et al.<sup>29</sup> identified nine types of potential impacts PRO trials can have; they include: informing clinical practice, informing clinical guidelines, informing health policy, supporting drug approval, supporting pricing and supporting reimbursement decisions, informing clinical and shared decision-making, and informing consent for treatment. Given the number of patients certified for medical marijuana in Florida and the gaps in science, with its focus on complementary care and cannabis science, the CC-PBRN is poised to make a significant scientific contribution.

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## Ethical approval

IRB approval for this study was obtained via Florida State University Institutional Review Board.

## Consent to participate

Appropriate consent to use the de-identified EHR data in this manuscript was obtained.

## Authors' contributions

All authors made substantive contributions to the development, design and writing of this manuscript. Dr. Ennis led the development, conceptualization, data analysis plan, interpretation of findings and writing of the manuscript. Dr. Vance provided clarification on the meaning of raw data fields, interpretation of analyses, and contributed to the writing, and Mr. Bradbury was responsible for all data management (the data structure was transformed from the EMR and managed in SAS), completion of all data analyses, and contributed to interpretation of data and writing of the manuscript.

## Conflict of Interest Statement

Nicole Ennis, PhD and Russell Bradbury, MS have no conflict of interest to report. Cameron Vance, PharmD is a co-founder of MMTC Florida.

## Author's statement

This manuscript is original work. This manuscript has not been published in any other journal and is not under consideration for publication in any other journal. This work was supported by pilot funding from Florida State University awarded to Nicole Ennis, PhD as indicated in the declarations on the title page.

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## Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at [doi:10.1016/j.ctim.2022.102821](https://doi.org/10.1016/j.ctim.2022.102821).

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