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Regulatory uncertainties of tokens

The regulatory status of tokens and distributed ledger technology is unclear. It is difficult to predict how or whether regulatory authorities may apply existing regulation with respect to such technology. It is difficult to predict how or whether the regulator may implement changes to the law and regulation affecting distributed ledger technology and its applications, including the RWD Tokens, RWE Tokens and the Embleema healthcare Blockchain network. Regulatory actions could negatively impact the functionalities of the RWD Tokens, RWE Tokens and the Embleema healthcare Blockchain network in various ways, including, for purposes of illustration only, though a determination that the purchases, sale and delivery of the RWD Tokens and RWE Tokens constitute unlawful activity or that the RWD Tokens and RWE Token are regulated instruments that require registration, or the licensing of some or all of the parties involved in the purchase, sale
and delivery thereof. The Embleema healthcare Blockchain network will not be used and may cease operations in a jurisdiction in the event where that regulatory actions, or changes to law or regulation, make it illegal to operate in such jurisdiction, or commercially undesirable to obtain the necessary regulatory approval(s) to operate in such jurisdiction.

**RWD Tokens and RWE Token are not financial instruments**

RWD Tokens and RWE Tokens do not represent an investment in a security or a financial instrument within the meaning of EU Directive 2014/65/EU of the European Parliament and of the Council of 15 May 2014 relating to markets in financial instruments: the RWD Tokens and RWE Tokens confer no direct or indirect right to Embleema’s capital or income, nor does it confer any governance right within Embleema.

**RWD Tokens and RWE Token are not proof of ownership or a right of control**

They do not confer any right on any asset or share in Embleema. RWD Tokens and RWE Tokens do not grant any right to participate in control over Embleema’s management or decision-making set-up.

**RWD Tokens and RWE Token are not electronic currencies**

within the meaning of EU Directive 2009/110/EC of the European Parliament and of the Council of 16 September 2009 relating to access to and pursuit of the business of electronic currency institutions: RWD Tokens and RWE Tokens do not have a fixed exchange value equal to the amount delivered at the time of its issue.

**RWD Tokens and RWE Token do not qualify as payment services**

within the meaning of EU Directive (2007/64/EC) of 13 November 2007 relating to payment services in the internal market, nor within the meaning of the (EU) Directive relating to payment services 2 (DSP 2) N° 2015/2366 of the European Parliament and of the Council of 25 November 2015: the Founder’s Token Sale (the “Crowdsale”) does not only involve the sale of RWD Tokens and the Embleema’s business does not consist in receiving currencies against the delivery of RWD Token; as such, a RWD Token is not a means of payment either.

**RWD Tokens and RWE Tokens are cryptographic tokens used through the Embleema healthcare Blockchain network**

RWD Tokens and RWE Tokens are crypto-currencies, i.e. unregulated, digital assets, issued and controlled by its developers, and used and accepted only by the members of a given community.
Intellectual property belonging to Embleema

The Purchaser acknowledges that Embleema retains sole and exclusive ownership of all intellectual, industrial and expertise rights relating to the RWD Tokens and RWE Tokens, documents, data, etc. The technical and technological resources and expertise used to design both the RWD Tokens, RWE Tokens, and documents of any nature, shall remain the exclusive property of Embleema regardless of whether they are protected under an intellectual property clause. Therefore, any document, listing, database, etc., in its entirety, is given to the Purchaser in return for payment or free of charge solely as a loan for use that exclusively enables them to use the Embleema healthcare Blockchain network, under or not a separate availability and/or non-disclosure agreement that forms an integral part of the T&C, and may not be used by the Purchaser for any other purpose without incurring their liability.

Protection of Personal Data

The processing of personal data performed under the Crowdsale will be provided in France to the National Commission for Data Protection and Liberties upon request.

In accordance with Article 32 of French law N° 78-17 of 6 January 1978 relating to Information Technology, Files and Civil Liberties and the General Data Protection Regulation (2016/679) Embleema, which is responsible for processing the said data, will inform the Purchaser that it is processing their personal data. The details entered by the Purchaser on the forms available on the website are intendeds for authorized personnel for administrative and business management purposes. These data are processed to allow Purchasers to access the Crowdsale.

- The Purchaser is entitled to access, question, modify, rectify and delete its own personal data,

- The Purchaser is also entitled to object to the processing of their personal data for legitimate reasons, as well as to object to the use of such data for the purposes of prospecting activities.

To exercise their rights, the Purchaser shall notify their request to Embleema, attaching a copy of their signed ID document.

The Purchaser shall comply with the provisions of French law N° 78-17 of 6 January 1978, as amended, relating to Information Technology, Files and Civil Liberties and the General Data Protection Regulation (2016/679), any
breach of which is deemed a criminal offence. In particular, they shall not collect or misuse data and, in general, perform any act likely to infringe the privacy or reputation of individuals.

Regulatory uncertainties

The Purchaser acknowledges and accepts that the Crowdsale launched by Embleema is taking place within a French legal environment that is still under development. New laws or rules may subsequently frame, modify or clarify the practice of such Crowdsale. Where necessary, should legislative changes conflict with all or part of these T&C, Embleema reserves the right to amend the terms of the Crowdsale as appropriate, retroactively if necessary, in order to ensure that the Crowdsale remains legal and compliant with the various French regulatory bodies.

Embleema will respond to any request issued via regular legal process aimed at obtaining specific information about the Purchasers, particularly in terms of the fight against money laundering.

Purchasers of RWD Tokens must seek appropriate financial, tax and other legal and regulatory advice from independent financial advisors with appropriate qualifications to determine whether the purchase of the RWD Tokens is adapted to their own situation and authorised for subscription under their own legal and regulatory rules. Any decision to purchase the RWD Tokens should be based on the information contained in the White Paper and the T&C which includes, inter alia, information on certain risks associated with the purchase of the RWD Tokens. Purchasers shall pay attention to the Section “Risk” of the T&C to assess the risk linked to the purchasing of the RWD Tokens.

Applicable law and jurisdiction

These T&C and any contract relationship relating to the network set-up by Embleema are governed exclusively by French law, the Embleema’s commitment being subject to this clause.

Embleema and the Purchasers agree to seek an amicable settlement prior to bringing any legal action. Failing this, any dispute, of any nature whatsoever, will be brought expressly before the court with jurisdiction over the Embleema’s registered headquarters in France, as no document can affect a novation or waiver of this jurisdiction clause.
After launching its Version 1 of its Health Blockchain Network on July 17th, 2018, Embleema¹, is introducing Version 2 of its Health Blockchain Network that connects dispersed Patient Generated Health Data (“PGHD”), Electronic Medical Records (“EMRs”) and other sources of patient information into a consolidated and highly-secure repository, providing the healthcare ecosystem an undisputed and 360 degree view of the patient’s medical history and thus setting the foundation for the delivery of safer, better and personalized medicine.

In addition to clinical benefits for patients, Embleema Health Blockchain Version 2 gives control back to the patient of his/her health records, secures his/her explicit, enlightened and traceable consent for sharing them, and provides him/her potential compensation when his/her information is used for clinical research and Real-World Evidence (“RWE”) when allowed by local regulation.

Embleema Health Blockchain Version 2 also allows other owners of the patient’s health records, to securely share his/her data to data buyers and receive potential compensation for it, at the condition the patient has provided explicit consent to do so beforehand. With this ability to consolidate all patient data types such as EMRs, PGHD, genomics, biomarkers, lab results data, connected medical devices generated data from all data owners, Embleema Health Blockchain Version 2 provides comprehensive, continuous, individual-patient level data, setting the standard for the next-generation of high-resolution Real-World Evidence for a safer, more effective and more personalized medicine: patients can share their comprehensive medical record with their physicians and help them make better treatment decisions, patients having exhausted existing treatment options can expose their data to identify clinical trials they can enroll in, patients can also directly feed their reported outcomes as valuable input to measure efficacy, health authorities and pharmaceutical companies are able to continuously monitor in real-time and at individual-patient level the safety and efficacy of drugs, health providers can continuously measure patient outcomes and improve their practice.

¹ A U.S. Delaware C-Corporation
Embleema Health Blockchain Version 2 will include nodes from stakeholders of the healthcare ecosystem such as care networks, pharmaceutical companies, patient advocacy groups and authorities, allowing each node provider to be potentially compensated with transaction fees, conditioned to each node provider complying to local regulations regarding health data privacy.

Third-party patient apps can access Embleema Health Blockchain Version 2 through open smart-contract APIs and offer personalized services to patients by using their health history with their prior and explicit consent.


Led by Robert Chu, former SVP of Global Technology at IMS Health, the global leader in health data and real-world evidence and a leadership team of seasoned executives in healthcare and technology, after demonstrating its business and technical abilities with the public release of Embleema Health Network V1 in July 2018, Embleema has the know-how and relationships in the U.S., European and Asian healthcare industry to successfully bring V2 to market and set the standard for the next-generation of Real-World Evidence, for a safer and more efficient health system.
The Medical Record Sharing Issue

While the U.S. Department of Health and Human Services Centers for Medicare and Medicaid Services (CMS) Meaningful Use incentives drove 95% of the hospitals in the U.S. to adopt Electronic Medical Records over the past 10 years (Office of the National Coordinator for Health Information Technology, Data Brief 35, May 2016), it was not designed to drive interoperability and sharing of medical records. As a consequence, current methods for sharing and distributing patient medical data from one provider to another are inefficient and costly to implement, and crucial medical records fail to be properly distributed to each segment of a patient’s treatment pathway.

This distribution failure results in poor clinical outcomes, increased healthcare costs and potentially poses safety risk. As an example, a U.S. study in colon cancer treatment found that better sharing of medical data could lead to cost savings of approximately 30%\textsuperscript{2}. Similarly, a recent French study from the Caisse Nationale d'Assurance Maladie, France’s national healthcare payer, disclosed that 128,000 hospitalizations in France are caused each year by drug interaction effects, hospitalizations that could be mitigated or prevented by the proper access and distribution of the patients’ medical records.

The Cyber-Security Issue

The Office of Civil Rights of the U.S. Department of Health and Human Services reported that more than 15.5 million Electronic Medical Records were breached in the U.S. in 2016, a staggering number. Patient medical records are lucrative targets for hackers and cyber-thieves. According to Experian, an EMR is worth approximately $500 on the black market, which is 10 times more valuable than a credit card number. A Ponemon study estimates the healthcare industry spent $6.2 billion in 2016 to deal with healthcare data breaches. With the rise and prevalence of “ransomware” and increased frequency of cyber-attacks, it is imperative that patients’ valuable medical records are kept in a secure online environment.

\textsuperscript{2} Study from Hoverman Jr., Cartwright TH, Patt DA: Pathways, Outcomes and Costs in Colon Cancer, 2011
Dr. Scott Gottlieb, Commissioner of the U.S. Food and Drug Administration ("FDA"), highlights the importance of Real-World Evidence for improving the quality of patient treatment and public health in his July 18th, 2018 blog:

“In addition to the FDA’s increased requirements on richer and deeper RWE for real-life safety and efficacy monitoring, pharmaceutical companies also are encouraged to submit their RWE as early as in pre-launch clinical trial phases, as part of the 21st Century Cures Act ("Cures Act") which aims at accelerating clinical drug development and making drugs available earlier to patients.

Because of the current lack of sharing of medical information, pharmaceutical companies are forced to rely on labor-based methods for RWE collection, involving third party service companies who recruit health providers who in turn recruit patients into a RWE study and interact with each recruited patient to collect RWE with a high unpredictability on the quality of the data. Other methods of RWE studies called retrospective database studies rely on secondary databases, such as patient registries, which carry significant limitations such as lack of key data attributes (e.g. biomarkers for targeted therapies) and methodological challenges (e.g. confounding, selection bias)

Current RWE methodologies are therefore slow, costly and yield uncertain and low-resolution results, deepening the sense of frustration from the health regulators who expect faster and more precise results from the pharmaceutical companies who are limited by current RWE practices.

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The 21st Century Cures Act (2016) aims to accelerate regulatory approval and go-to-market, incorporating perspectives of patients into development of drugs & devices in FDA's decision-making process.

The EMA’s “adaptive pathways” approach (2016) supports Real World Evidence (RWE) as a mean to improve timely access for patients to new medicines and monitor impact.
Furthermore, because of the high-degree of labor and the many intermediaries required to collect this data, all of the economical benefit of the RWE market which is expected to grow to $1.7 billion by 2023\(^6\) goes to RWE service companies, care centers and health providers, with patients receiving a negligible benefit if any. Similarly to the Facebook business model where users generate the data but do not receive any rewards out of the $5 billion quarterly profit generated by their data, the RWE market is highly centralized in terms of value capture and patients who generate the data are not receiving a legitimate compensation for it.

To make things worse, patients are most of the time not aware that their data, even de-identified, is used in retrospective database studies. In Europe, such RWE databases may carry a risk in term of compliance to the notice given to patients under the GDPR privacy regulation (General Data Protection Rule).

Current methods of getting RWE are costly, slow and inefficient

Current Real World Evidence (RWE) Studies Shortcomings

- **Lenghty process:** After drug launch, contract research organizations (CROs) take more than one year to manually collect and compile real world data from different industry silos with an incomplete view
- **Costly process:** Per patient cost of trials is $36,500 in average & $16,500 for phase 4
- **Patients are not compensated when their aggregated data is sold as RWE to pharma**
- **Risk on patient consent:** Patient don’t know how their data is used, despite legal obligation to notify at least in the EU (art. 6 of GDPR)

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Blockchain Technology and Healthcare

Blockchain is a shared, distributed database with very strong data integrity properties, making the technology very suitable to protect and share sensitive healthcare information. When stored in Blockchain, health records maintain their integrity and can therefore be shared between patients, providers and other stakeholders in a trusted manner. Similarly, storing the patient’s consent to share his/her data in the Blockchain allows strong, traceable privacy protection for the patient. Furthermore, the distributed nature of Blockchain nodes is well suited to interface with the myriad of dispersed health record databases. Embleema Health Blockchain chains and stores securely a patient’s health records wherever they sit, reconstructs them into a trusted, comprehensive medical history that can be shared by patients amongst the entire healthcare ecosystem: healthcare professionals, primary care practices, health systems, hospitals, health insurance providers, healthcare authorities, pharmaceuticals and medical device manufacturers.

Embleema Health Blockchain provides control to patients of his/her health records, whether they are owned by him/her or other data owners such as hospitals, healthcare providers, research centers, medical laboratories and other third-party vendors. Patients and data owners can also sell their de-identified patient records and receive compensation from data buyers, when local regulation authorizes such business agreements.

Embleema Health Blockchain offers to the health system the next-generation of RWE: real-time, individual-patient level 360 view medical histories, with continuous monitoring of the same patient, and his full and trusted consent, fulfilling the vision of the U.S. FDA for an “effective use of real world data and real world evidence (that) will have a profound impact on individual patients and the public health.”
Embleema’s Solution
The Embleema Health Blockchain Network

Embleema’s decentralized Blockchain network connects a patient’s dispersed health records from his/her:

- various care centers, such as hospitals, primary care practices, rehabilitative centers, nursing homes, medical laboratories and urgent care centers,
- connected devices, such as wellness and medical devices,
- reported outcomes and other self-reported health information,
- genomics and disease-specific data (e.g. biomarkers, tumor type in oncology)

and chains them into a meaningful, comprehensive, and highly secure patient record.

As such, Embleema Health Blockchain is open to all healthcare stakeholders generating and consuming patient medical information such as patients, health providers, health systems and care centers, insurance providers, healthcare authorities, pharmaceuticals and medical device manufacturers, provided they comply with patient data privacy and data security regulations, such as HIPAA in the U.S. and GDPR in the E.U.

Other participants to the Embleema Health Blockchain are:

- “Node providers” who own and operate one or several nodes of the Embleema Health Blockchain. Each node contains the entire Blockchain and can also mine the Blockchain in a round-robin Proof-of-Authority protocol, which rewards them with transaction fees paid by network participants when they store data on the Blockchain. Node providers will be permissioned by Embleema, as compliance to local regulation regarding data privacy and/or health data storage needs to be validated before accepting a new node to the Blockchain,
- Distributed App (Dapp) developers who provide personalized services to patients based on the patient record stored on the Blockchain. Such services can be assisting the patient in following his treatment plan, providing information on his disease, connecting him to other patient groups with similar conditions or clinical

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7. Mining is the action of writing new data in the Blockchain with a high level of data integrity
trials he can access, or suggesting programs for weight loss and exercise. Dapp developers also need to be fully compliant with patient data privacy and security regulations prior to accessing the Blockchain smart-contracts and patient medical histories.

The Embleema Health Blockchain contains de-identified health records. Strong de-identification algorithms will be implemented in the Blockchain ensuring full compliance versus data privacy regulations such as HIPAA on Protected Health Information in the U.S. and GDPR Article 6 on the lawful processing of personal data. The Embleema Health Blockchain will also comply with any additional local regulation pertaining to either data privacy or health data processing. Re-identification risks, notably in small patient populations, will be particularly scrutinized and patient records bearing such risk will carry additional safeguards when stored in the Blockchain and will not be exposed in the Marketplace.

**Data Architecture**

A “health record” in Embleema Health Blockchain is always at patient-level, de-identified and is defined as:

- a text-based, coded set of health information collected during an encounter (allergies, medications, problems, procedures, social history, results, immunizations, vital signs, provider notes). The text-based, coded set of health information is entirely stored on the Blockchain,
- a text-based index describing the content and access method to an off-chain electronic file containing health information such as images, scans, genomics data, associated with the hash of the off-chain electronic file. Only the index and hash are stored on the Blockchain,
- a health record is owned by a « data owner » and assigned a « price » in tokens by the data owner (see Marketplace), a « transaction fee » is paid by the data owner of the health record to the miner when his health record is mined into the Blockchain,
- a health record will be tagged as « medical » if produced and/or signed by a healthcare professional, or will be tagged as « patient generated health data » for all other types of health records.

The patient’s public key links the different health records related to him on the Blockchain, these linked health records belonging to a given patient is defined as a “patient record”. Health records within a patient record may belong to several data owners.
Embleema Health Blockchain

Data Architecture

Medical Data:
- Codes (LOINC, SNOMED, ICD-10, CPT-4...)
- Healthcare professional notes

Patient Generated Health Data:
- Connected devices (low volume), PRO

Individual, longitudinal and de-identified

Data Sources:
- Connected Devices Data (High volume)
- Imaging
- Patient Registries
- Genomics

Care Centers, Research Centers, Labs:
- EMR
- Images
- Genomics
- Molecular Data
- Biomakers

Health Record

Data Owners:
- Patient
- Care center
- Medical Lab

Embleema Health Blockchain

Data Ownership

Patient A

Health Record

Health Record Sources:
- Connected Devices Data (High volume)
- Genomics
- Biomarker Data
The Marketplace: Data Owners and Data Buyers

Blockchain allows P2P trading of fully owned digital assets

- **Data Owner**
  - Patients
  - Care Centers

- **Researcher**
  - Life Sciences

- **Regulators**
  - (e.g., FDA)

*Match buyer & seller who agree on transaction & rules in contract coded in Blockchain*

*Network of nodes validates transaction & updates chain of blocks*
Embleema Health Network will run a Marketplace smart-contract allowing “data owners” to expose their health records in the Marketplace as available for purchase and allowing “data buyers” to match their data requirements with the available data on the Blockchain and execute a purchase using RWE tokens.

- A “data owner” is a network participant who owns the health record of a given patient and stores it in the Blockchain. However, the patient controls the sharing of his/her patient record and the health records making up his/her patient record. The patient is the only one who authorizes the sale of his/her patient record to a «data buyer». If the patient authorizes the sale of his/her patient record, each data owner who owns a health record making up the patient record is paid in tokens by the data buyer.
- A “data buyer” is a network participant who buys patient records made of health records from their respective data owners through the Marketplace.
A “data quality agent” is a network participant who performs a quality check and transforms the quality of a health record from “patient generated health data” to “medical”. Patients can request data quality agent to perform this quality check as medical health record usually carries more value than a patient generated health data record.

Depending on local regulation:

- possible “data owners” are patients, providers, care centers, pharma or payers,
- possible “data buyers” are pharma companies, payers, Dapp providers,
- possible “data quality agents” are providers.

Initially, each patient declares in the Marketplace his/her consent in terms of which health records he/she wants to expose, for what period of time, for what usage, to which data buyers. Next, the Marketplace exposes in a de-identified manner the terms set by the patient and the price of each health record set by the data owner, as well as a meta-description of the patient record using dimensions such as disease, age group, geographical zone, treatment regimen and other relevant dimensions depending on the disease. Once the patient record’s metadata is exposed on the Marketplace, data buyers will query the Marketplace using their patient record inclusion criteria which are desired values for each dimension. The Marketplace will respond to the query of the data buyer by returning a number of patient records matching his inclusion criteria and the corresponding public addresses of the data owners (anonymous). The data buyer decides and selects amongst those data owners which health records he wants to purchase and executes the purchase using RWE tokens.
The RWE Token

RWE Token Utility

Embleema Health Blockchain requires RWE tokens for participants to use certain features of the Blockchain. The RWE token provides the following rights to participants:

- **For data owners:** access the Blockchain to store, share, improve the quality of their health records, sell their de-identified health records on the Marketplace, and receive potential compensation in RWE tokens if they store and share their health records on the Blockchain,
- **For data buyers:** access the Blockchain Marketplace to purchase health records, and pay their purchases using RWE tokens,
- **For data quality agents:** access the Blockchain to perform health record quality checks and receive compensation in RWE tokens for doing so,
- **For miners:** receive transaction fees in RWE tokens for their mining on the Blockchain.
A Minimum Token Ownership (MTO) is required by the Blockchain to run the Marketplace features, while other features of the Blockchain can be accessed without mandatorily detaining RWE tokens: data owners and data buyers need to maintain in their RWE account a balance of RWE tokens superior to the MTO in order to access the Marketplace features.

Possible RWE token flows are summarized below:

**Embleema Network Participants and Token Flows**

- For the first 3 years, data owners get compensated by the Embleema Health Blockchain with 60 RWE for each health record added to the Blockchain, encouraging more data owners to join the Blockchain and add health records to the Blockchain.
- Each time a data owner stores a health record on the Blockchain, he will pay a transaction fee of 10 RWE to the miner, encouraging more miners to add nodes to the Blockchain.
- Each time a data owner asks for a quality check of a health record by a data quality agent, the data owner will compensate the data quality agent with 150 RWE per health record.
- Each time a data quality agent performs a quality check on a health record, he will pay a 10 RWE transaction fee per health record to the miner.
- Starting beginning of year 3, data owners and data buyers may join the Marketplace provided they own more RWE tokens than their MTO. The MTO for data owners is 120 RWE per patient record and the MTO for data buyers is 250,000 RWE per enterprise (pharma, payer). Data buyers purchases health records from data owners on the Marketplace at the price set by the data owner.
• Data buyers may buy RWE tokens from token owners to fund their data purchases. Token owners are data owners who receive tokens as compensation for the sale of their health records, data quality agents who receive tokens as compensation for their quality improvement work, miners who receive tokens as compensation for their mining (transaction fees). Other token owners are RWE token owners who have purchased tokens during the Founder’s Token Sale (see Token Generation Event section), and Embleema management, employees and advisors who receive tokens as incentives (see Company Time-Locked Tokens section).

**Token Economics**

The graphs below represent the net flow of RWE tokens per participant using the following assumptions:

- Patient Records: 1.6 million in Year 5, half are owned by Patients, and half owned by Care Centers (see Go To Market Strategy for patient count),
- A Health Record is added every month to each Patient Record,
- 20% of Patients will ask for a quality check on half of their Health Records,
- Pharmas are buying a Patient Record at an average price of 2,500 RWE per year
- Payers are buying a Patient Record at an average price of 1,000 RWE per year
- Pharmas, Care Centers and Payers are providing 30% of the mining capacity in Year 5

**RWE token Flows Per Participant Per Year**

*(RWE Token Fixed Value)*

![Graph showing token flows per participant per year](image-url)
Benefits to the Health Systems

For patients, benefits are two-fold:

- when sharing their identified, comprehensive medical history to providers, providers will make better-informed and safer treatment decisions, no RWE tokens are required from patients to use this feature,
- when sharing their de-identified patient records, patients will directly contribute to advance research and real-life monitoring by providing valuable data, and benefit financially from it, while fully in control of their data.

For providers, having at the tip of their fingers a 360 view and comprehensive medical history of all available health data for their patients will cut down the administrative time to manually reconstruct patient medical histories and allow them to make fully informed decisions on their patients’ next treatments. No RWE tokens are required from providers to benefit from this feature. Providers also have the opportunity to receive compensation for improving the quality of health records in the Blockchain.

Care centers can diminish safety issues and associated additional costs by better understanding their patient’s pathways and outcomes. Blockchain also provides them with a highly secure IT storage solution for their essential medical information and helps them fulfill HIPAA requirements by having the full audit-trails of patient information accesses.

Pharmaceutical companies and Medical Device Manufacturers have the next-generation of Real-World Evidence and the ability to:

- access precise, individual-patient level data,
- continuously monitor of the same patient,
- ensure explicit and enlightened consent from each patient.

By sharing this same high-resolution data with authorities, Pharmaceutical companies and Medical Device Manufacturers have an opportunity to share transparently the same data, and start bridging the trust gap between them and the authorities.

With this real-time, comprehensive, individual-patient level data, Authorities can accelerate their assessment regarding drug efficacy and safety, and release faster approvals for new drugs, offering patients earlier access to the latest therapies.
Implementation
Embleema Health Blockchain Version 1

Embleema released its public version of the Embleema Health Blockchain Version 1 on July 17, 2018.

Embleema has already launched the first patient Blockchain

PatientTruth, the first live Patient Blockchain app that lets patients store and share their RWE securely

- Aggregation of health data
- Full auditability & traceability for patients
- Marketplace research
- Smart contracts
- Tokenization of data
Version 1 is publicly accessible at https://patienttruth.embleema.com and contains the following functionalities:

- Upload HL7 Continuity of Care Documents (CCD) medical records into blockchain by patients (U.S. patients only),
- Upload of Fitbit information into blockchain by patients,
- Consolidation of CCDs (U.S. patients only) and Fitbit information into a Medical history stored securely on blockchain,
- Authorization management from patients for the sharing of their Medical history with providers,
- Visualization by providers of patients’ Medical histories after due authorization from patients,
- Audit-trail for patients of Medical history accesses by providers,
- Compensation to patients in EBL tokens for uploading CCDs (U.S. patients only) and Fitbit information, as well as referrals of new patients and providers.

Version 1 will be used to pilot and prove in real-life the relevance of the 2 key concepts carried by the Embleema Health Blockchain:

- Patients have control of their health records and may share and sell their data to pharma companies: this pilot will start in September 2018 with cysticfibrosis.com, a U.S. based patient community in Cystic Fibrosis (announced on July 17, 2018: https://medcitynews.com/2018/07/embleema-emerges-from-stealth-mode-launches-blockchain-based-health-record-system/),
- Pharma companies and regulators share the next generation of RWE: real-time, individual-patient level 360 view medical histories, with continuous monitoring of the same patient and his/her full and trusted consent: this pilot will start in January 2019 with a top-5 global pharma company and a leading health regulator (announcement planned in Q4 2018).
Embleema Health Blockchain Version 2 contains the following features:

- Healthcare specific smart contracts managing patient consent, health record storage, patient record storage and sharing (identified and de-identified), patient record access audit-trail and the Marketplace,
- Built-in RWE token generated by the Blockchain for transaction fees and other rewards. RWE token transactions require no “gas” fee payment from the sender and have a predictable mining time,
- APIs and health record parsers to integrate into the Blockchain various data format inputs for health records such as HL 7 FHIR, CCD, proprietary connected devices formats and other health record format,
- Scalability: up to 2 million patients for the U.S. market place,
- Performance: visualization of health records should occur under 2 seconds, mining in the Blockchain should occur under 5 seconds, reconciling data buyers with data owners inclusion criteria in the Marketplace should occur under 1 minute, other batch processing such as data sources parsing and indexing will be assessed in terms of performance for each data source.

Smart-contract exposed to the network participants are:

- Health Record: write, read a health record in the Blockchain,
- Patient Record: connect health records to a given patient, read the patient record from the Blockchain,
- Patient Consent: defines patient’s authorization to share his health records (identified and de-identified),
- Audit Trail: provides data owners audit-trail on accesses to their health records,
- Marketplace: exposes data owners health records meta-data after due authorization from patients, allows data buyers to search health records for purchase, matches data buyers’ inclusion criteria with data owners records, executes purchase transactions between data buyers and data owners,
- RWE token smart-contract: issues RWE tokens as rewards for data owners for storing health records in the Blockchain (first 3 years).
Functional Description

Patients can:

• Register and sign-on through the Patient Dapp interface,
• Upload their health records in the Blockchain,
• Visualize their patient record,
• Authorize the sharing of their identified patient record to providers,
• Expose and sell their health records in the Marketplace against RWE tokens,
• Visualize a full audit-trail on their patient record access and health records sold,
• Visualize a statement of his/her RWE transactions.

Providers can:

• Register and sign-on through the Provider Dapp interface,
• Visualize an identified patient record, with due consent from the patient,
• Perform a health record quality check, when requested by the health record data owner,
• Visualize a statement of his/her RWE transactions,

Care Centers and other Data Owners can:

• Register and sign-on through the Data Owner Dapp interface,
• Have their health records indexed into the Blockchain and linked to patients,
• Expose and sell their health records in the Marketplace against RWE tokens, with due consent from the patients,
• Visualize a statement of RWE transactions,

Pharma companies, Payers and other Data Buyers can:

• Register and sign-on through the Data Buyer Dapp interface,
• Expose their inclusion criteria for health record purchases,
• Browse a list of data owners which own health records matching their inclusion criteria,
• Select the data owners they wish to purchase health records from,
• Execute the purchase in RWE tokens with data owners,
• Visualize a statement of RWE transactions,
Pharma companies and authorities can:

- Register and sign-on through the Real-World Evidence Dapp interface,
- Pharma companies register health products on which they wish to share with authorities Real-World Evidence, and define the patient records they wish to share,
- Authorities can visualize the shared Real-World Evidence from Pharma companies,

We expect Version 2 to be HIPAA compliant (see “Embleema and Privacy Compliance section” below) for the U.S. users and GDPR compliant for the European users. Version 2 will include health records from U.S. patients. Version 2 is planned to launch in Q3 2019.

Subsequent Versions and Expansion

End of 2019, Embleema expects to expand its Blockchain to the French market and the China marketplace with its 800 million connected patient population by striking a set of strategic distribution partnerships with major local players in the healthcare and technology industry.

Concurrently to its V2 launch in Q3 2019, Embleema plans to set up consulting services for pharmaceuticals and health network to facilitate the adoption of blockchain in their processes and systems.

In 2021, Embleema plans to launch V3 of its Health Blockchain Network which will able to integrate mining nodes from pharma companies, payers and care centers. V3 will also implement an API allowing third party patient app providers to connect to the Blockchain and offer personalized services to patients through the Blockchain.

For 2022, with a critical mass of patient records stored onto the Blockchain, Embleema plans to offer advanced analytics services for various purposes: population health, observational studies, safety studies. Embleema will also start researching the possibility of offering predictive medicine services based on the wealth of data stored in the Blockchain.

The following figures illustrate Embleema’s growth plan and milestones.
Milestones

Product Development

2017
- May 2017: Embleema incorporated
- October 2017: PatientTruth Prototype completed / Positive customer reviews

2018
- January 2018: A. Al-Saleh, B. Gilly and F. Duchesne join Advisory Board
- Dr. John Halamka joins Advisory Board
- July 2018: V 1.0 launched: 1st Patient & Provider Dapp
  IP: Data parser & consent/audit trail smart contract

2019
- Series A Equity Event
- July 2019: V 2.0: RWE decentralized marketplace & app
  IP: Marketplace smart contract
- Q3 2019: Embleema Consulting Services

Demand

- September 2018: Cystic Fibrosis Pilot #1
- Q3 2018: Angel Equity Event Completed
  Token Sales under Loi Pacte
- November 2018: Big Pharma Pilot #2

Growth

- Q2-Q4 2018: Adapt UX/UI with real customer pilots
  IP: Wallet Management System

Expansion

- Q3-Q4 2019: Planned launches in France & China

- Company
- Product, barriers to entry & IP
- Customers
Embleema plans to reach 200 employees in Q4 2021.

250,000 patient records planned on the Marketplace in Q4 2021.

V 4.0: Analytics Population Health Predictive Medicine

Embleema plans to reach 400 employees in Q4 2022.

700,000 patient records planned on the Marketplace in Q4 2022.

1,600,000 patient records on the Marketplace in Q4 2023.

Company

Product, barriers to entry & IP

Customers
Go To Market Strategy

Our patient and other data owner recruitment on our Blockchain is executed by disease area. In addition to Cystic Fibrosis which we already started with the agreement signed with cysticfibrosis.com in July 2018, we are planning to develop the 5 following disease areas on the Embleema Health Blockchain:

- Multiple Sclerosis,
- Epilepsy (Pharmacoresistant),
- Hepatitis B,
- Crohn’s Disease,
- Chronic Lymphocytic Leukemia.

These disease areas were selected because of their relative low number of patients concerned, unmet medical needs and strong pipeline of drugs in clinical trials. Lower number of patients allows us to execute their recruitment in a reasonable period of time, patients with unmet medical needs often are highly motivated to share their data to advance research. Pharma companies with a strong pipeline of drugs in clinical trial phase are eager to access RWE to complement their clinical trial findings and accelerate the FDA’s approval cycle per the Cures Act.

For each disease area, we:

- Engage the patient advocacy groups and incent them to enroll their patient community to participate to the Blockchain. Rewards for storing their health records will incent the patients to store their health records in the Blockchain and participating to the Marketplace will compound additional compensation,
- Analyze the patient pathway to identify care centers they are treated in. We engage those care centers and incent them to participate the Blockchain by rewarding them to have their health record indexed and hashed in the Blockchain. Participating to the Marketplace will also compound additional compensation,
- Engage pharma companies who have existing or future drugs in the disease area to incent them to join the Blockchain as data buyers. Pharma companies often have deep relationships with care centers and patient communities in the same disease area and will also help in recruiting patients and other data owners to store their data in the Blockchain.
We are planning for the Embleema Health Network to store or index about 50% of all the patient records in these 5 disease areas at the end of Year 5 of operations, which represents a total count of about 1.6 million patient records.

<table>
<thead>
<tr>
<th>Disease Area</th>
<th>U.S. Prevalence (*)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CLL</td>
<td>130,000</td>
</tr>
<tr>
<td>MS</td>
<td>450,000</td>
</tr>
<tr>
<td>Crohn's Disease</td>
<td>600,000</td>
</tr>
<tr>
<td>Epilepsy (Pharmacoresistant)</td>
<td>800,000</td>
</tr>
<tr>
<td>Hepatitis B</td>
<td>1,200,000</td>
</tr>
</tbody>
</table>

(*) Embleema estimate
### Identify diseases with high data needs

<table>
<thead>
<tr>
<th>Disease</th>
<th>US Prevalence</th>
<th>Patient Advocacy Groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hepatitis B</td>
<td>1,200,000</td>
<td>hepb.org</td>
</tr>
<tr>
<td>MS</td>
<td>450,000</td>
<td>shift.ms</td>
</tr>
<tr>
<td>Crohn’s Disease</td>
<td>600,000</td>
<td>Crohnscolitisfoundation.org</td>
</tr>
<tr>
<td>Chronic Lymphocytic Leukemia</td>
<td>130,000</td>
<td>patientpower.info</td>
</tr>
<tr>
<td>Epilepsy (Pharmacoresistant)</td>
<td>800,000</td>
<td>epilepsy.com</td>
</tr>
</tbody>
</table>

### Engage patient advocacy, care centers & pharmas

<table>
<thead>
<tr>
<th>Disease</th>
<th>Nb of Drugs in Pipeline</th>
<th>Nb of Pharmas</th>
<th>Top Pharmas</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hepatitis B</td>
<td>112</td>
<td>73</td>
<td>Arbutus (10)</td>
</tr>
<tr>
<td>MS</td>
<td>179</td>
<td>97</td>
<td>Biogen (8)</td>
</tr>
<tr>
<td>Crohn’s Disease</td>
<td>152</td>
<td>75</td>
<td>Sanofi (6)</td>
</tr>
<tr>
<td>Chronic Lymphocytic Leukemia</td>
<td>136</td>
<td>68</td>
<td>Novartis (6)</td>
</tr>
<tr>
<td>Epilepsy (Pharmacoresistant)</td>
<td>114</td>
<td>67</td>
<td>Eisai (7)</td>
</tr>
</tbody>
</table>

### Enroll patients & data owners on V 2.0

<table>
<thead>
<tr>
<th>Disease</th>
<th>Nb of Drugs in Pipeline</th>
<th>Nb of Pharmas</th>
<th>Top Pharmas</th>
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<td>67</td>
<td>Eisai (7)</td>
</tr>
</tbody>
</table>

(*) Embleema estimate
Token Generation Events
A maximum of 500,000,000 RWE tokens will be issued for operating the Embleema Health Blockchain:

- A maximum of 150,000,000 RWE tokens will be allocated to subscribers of the Founder’s token sale that will start in September 2018 (see Founder’s token sale section),
- An additional 35,000,000 RWE tokens will be assigned to support the Founder’s token sale in terms of marketing actions,
- The other tranche of 315,000,000 RWE tokens will be issued to support the growth and operations of the Embleema Health Network Version 2:
  - 240,000,000 RWE tokens will be given by the Embleema Health Network to Data Owners as compensation for storing health records for the first three years,
  - 75,000,000 RWE tokens will be allocated to the Company’s employees and advisors as long-term incentives to grow the Blockchain (see “Company time-locked tokens” section)

The Table below summarizes the allocation of the RWE tokens:

<table>
<thead>
<tr>
<th>Allocation</th>
<th>Quantity</th>
<th>Planned Timing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Founder’s token sale</td>
<td>Max 150,000,000</td>
<td>Starting in Sept. 2018</td>
</tr>
<tr>
<td>Founder’s token sale marketing</td>
<td>35,000,000</td>
<td></td>
</tr>
<tr>
<td>Compensation for Data Owners storing their health records</td>
<td>240,000,000</td>
<td>Q3 2019 – Q2 2022</td>
</tr>
<tr>
<td>Company Time-Locked Tokens</td>
<td>15,000,000</td>
<td>Q3 2018 – Q2 2019</td>
</tr>
<tr>
<td></td>
<td>15,000,000</td>
<td>Q3 2019</td>
</tr>
<tr>
<td></td>
<td>15,000,000</td>
<td>Q3 2020</td>
</tr>
<tr>
<td></td>
<td>15,000,000</td>
<td>Q3 2021</td>
</tr>
<tr>
<td></td>
<td>15,000,000</td>
<td>Q3 2022</td>
</tr>
<tr>
<td>Total Token Allocation</td>
<td>Max 500,000,000</td>
<td></td>
</tr>
</tbody>
</table>
A Founder’s token sale is planned to start in September 2018 out of the Projet de Loi PACTE® ("Plan d’Action pour la Croissance et la Transformation des Entreprises") regulatory framework from the French Government which is under discussion at French Parliament’s level but which has not been voted yet at the time of the Founder’s token sale.

Proceeds of the Founder’s token sale will be used by Embleema Inc. for the development, promotion and launch of the Embleema Health Blockchain Version 2.

The token sold during the Founder’s token sale is the RWD, which is an ERC-20 compliant token issued, stored and transferrable on the Ethereum Mainnet. The maximum number of token sold during the Founder’s Token Sale is 150,000,000 RWD tokens, with each RWD token being valued at $0.20 US. Acceptable payment forms to purchase RWD tokens are Ether (ETH), Bitcoin (BTC), Bitcoin Cash (BCH), Euros (EUR) and U.S. dollars (USD).

The Founder’s token sale will initially be made through private token sale. RWD token buyers will need to supply an ERC-20 compliant wallet address to receive their RWD tokens. RWD tokens will be issued to the buyers’ ERC-20 compliant wallet address no later than 3 calendar weeks after the end of the private placement phase. RWD ERC-20 tokens will be automatically converted into the Embleema Health Network Version 2 RWE tokens on a 1 for 1 basis at the materialization of the Genesis Block of the Embleema Health Blockchain Version 2, planned for Q3 2019.

Company Time-Locked Tokens

Company time-locked RWE tokens will be provided to Embleema’s management, employees and advisors as a long-term incentive to develop, promote and grow the Embleema Health Blockchain.
Upon receiving a Company time-locked token grant, the recipient can unlock half of his RWE token grant 1 year after the grant date, and the remaining other half 2 years after the grant date. This mechanism allows the Company to provide a retention incentive for its key managers, employees and advisors. Every manager and employee at Embleema is eligible to receive a Company time-locked token grant.

**The Company time-locked token grant program will have an annual allocation:**

- 15,000,000 RWD ERC-20 tokens will be assigned to this program in the Q3 2018 – Q2 2019 period as the Company hires new employees. The RWD ERC-20 tokens will be converted to Embleema Health Network Version 2 RWE tokens when the Genesis Block materializes.
- 15,000,000 RWE tokens will be assigned each year in the subsequent years: 2019, 2020, 2021, and 2022.

**Use of Proceeds**

The proceeds obtained during the presale will be used to cover Embleema’s operating expenses at least until Q2 2019 when we expect to launch the Embleema Health Network Version 2.

**The planned operating expenses for this period are as follows:**

<table>
<thead>
<tr>
<th>Operating Expenses</th>
<th>Description</th>
<th>% of proceeds</th>
</tr>
</thead>
<tbody>
<tr>
<td>Management Team</td>
<td>CEO, CTO, CFO, Chief Client Officer, Chief Privacy Legal Officer, Chief Delivery Officer</td>
<td>13%</td>
</tr>
<tr>
<td>Product Development</td>
<td>Development Team</td>
<td>19%</td>
</tr>
<tr>
<td>Service Delivery</td>
<td>Cloud and Software Infrastructure, Data input support, Participants support, Embleema Consulting Services</td>
<td>29%</td>
</tr>
<tr>
<td>Sales and Marketing</td>
<td>Account Managers and Marketing Managers, Marketing campaigns, Events, Participant Lead Generation and Conversion, Thought Leadership</td>
<td>25%</td>
</tr>
<tr>
<td>Business Support</td>
<td>Legal costs, office cost, internal IT infrastructure, travel, general expenses</td>
<td>14%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>

A detailed description of the Management Team profiles, roles and responsibilities is provided in the “Leadership” section.
Embleema & Privacy Compliance
Embleema will host nodes of the healthcare Blockchain network and operate Dapps in the U.S. and be compliant with the provisions of the Health Insurance Portability and Accountability Act (HIPAA) as medical history information falls under the Protected Health Information (PHI) category.

**HIPAA Security Rule**

Embleema will implement the following features in its offerings to comply with the HIPAA Security Rule:

- Assign a unique user identification for each user,
- Implement a secure sign-on for accessing authorized medical history information,
- Implement an emergency procedure to access medical history information,
- Automatic logoff of the user after a timeout period,
- Apply strong encryption to medical history information,
- Provide a full secure, audit-trail of medical history creation, access and deletion,
- Implement integrity check for medical history information.

Physical safeguards as regards to facility access controls, workstation use and security, device and media controls will also be implemented within Embleema’s premises.

In addition to the above, a set of organizational and administrative measures will be enforced within the Company:

- Set-up security risk assessment and period reviews of risk mitigation plans,
- Define sanction policy in case of employee non-compliance,
- Conduct periodic reviews of Embleema’s Information System, of which authorization and data access audit trails,
- Designate HIPAA Security and Privacy officers,
- Set-up employee and subcontractor authorization system for handling medical history information,
• Publish Company security and privacy policies and provide periodic training and reminders to Company employees,
• Establish malware protection,
• Define security incident procedure and contingency plans,
• Define emergency procedure,
• Conduct periodic evaluation of Embleema’s overall security safeguards,
• Set-up Business Associates agreements.

**HIPAA Privacy and Breach Notification Rules**

In addition to the features listed above as part of the HIPAA Security Rules compliance, Embleema will also implement the following as required by the HIPAA Privacy Rules:

• Provide breach notification to the users subject of the breach,
• Disclose medical history information to the Secretary of Health and Human Services (HHS) upon request,
• Provide an auditable trail of medical history information disclosures, and proof that all disclosures were duly authorized by the user.

HIPAA Breach Notification Rule also requires us to notify the HHS of any breach, as well as the media and public for breaches affecting 500 users or more.

Similarly, we expect to comply with the E.U. General Data Protection Regulation at the time of its enforcement (May 25, 2018). Only Fitbit data will be ingested in Blockchain for E.U. based users.
Leadership

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Embleema is led by Robert Chu, former Senior Vice-President at IMS Health (now IQVIA), the global leader of health data and Real-World Evidence solutions. Robert joined IMS Health in 2007 and was promoted to General Manager, IMS Health France in 2011. In 2013, he was appointed President, China and Asia Pacific, overseeing IMS Health’s business in 20 countries. Prior to IMS Health, Robert had a distinguished career at IBM Corp. Robert has a Master’s Degree in Engineering from Ecole Polytechnique, the top engineering college in France, and as Master’s Degree in Computer Science from Ecole National Supérieure des Télécommunications. Embleema’s leadership profiles can be found at embleema.com/#aboutus

An Advisory Board provides strategic insight and guidance to the company’s management team. The appointed members of the Advisory Board are:

- Adel B. Al-Saleh, Member of the Board of Management of Deutsche Telekom AG and CEO of T-Systems;
- Frederic Duchesne, CEO of Pierre Fabre Pharmaceuticals;
- Bernard Gilly, Ph.D., Founder and President of iBioNext;
- Dr. John Halamka, Professor Harvard Medical School, CIO Beth Israel Deaconess

Before being appointed Member of the Board of Management of Deutsche Telekom AG and CEO of T-Systems effective January 1, 2018, Adel Al-Saleh was CEO of Northgate Information Solutions Group where he developed a turnaround strategy and drove a successful value creation program across Northgate’s three businesses. Prior to joining Northgate in 2011, Adel held various senior executive positions at IMS Health (market leader in healthcare informatics) and spent the first 19 years at IBM, holding a variety of senior leadership roles.

Mr. Frederic Duchesne serves as the Chief Executive Officer of the Pharmaceuticals Division of Pierre Fabre, serving patients in more than 130 countries. He also serves as Managing Director Pharmaceuticals of Pierre Fabre Investment Arm and is a Member of the Board of the European Federation of Pharmaceutical Industries and Associations (EFPIA). Prior to joining Pierre Fabre in 2010, Frederic held senior executive positions at GSK in the UK and France.
Mr. Bernard Gilly, Ph.D. has over twenty years of experience in the financial and biotech sectors. He co-founded several disruptive technologies start-ups and is currently Chairman of Pixium Vision (2011), EyeTechCare (2012), Gecko Biomedical (2013) and Chronocam (2015). From 2005 to 2009, he founded and was Chairman and Chief Executive Officer of Fovea Pharmaceuticals, a privately owned biotech company, which was acquired by sanofi in 2009. After the acquisition, he became Senior Vice-President of the Ophthalmology Division of Sanofi until 2012. Prior to Fovea, Dr. Gilly was a partner at Sofinnova Partners from 2000 to 2005.

John D. Halamka, MD, MS is Chief Information Officer of the Beth Israel Deaconess Medical Center, Chief Information Officer and Dean for Technology at Harvard Medical School, Chairman of the New England Health Electronic Data Interchange Network (NEHEN), CEO of MA-SHARE (the Regional Health Information Organization), Chair of the US Healthcare Information Technology Standards Panel (HITSP), and a practicing Emergency Physician.
Conclusion
By returning control of health records to patients, Embleema Health Network allows the health system to deliver better care to them and rewards them for directly contributing to the improvement of healthcare by sharing their health data.

Embleema’s management team and advisors total more than a 100 years of professional experience in healthcare and technology, and are well connected to senior healthcare stakeholders across the US, Europe and Asia-Pacific. As a pure vertical player with deep experience regarding specific dynamics proper to the healthcare industry such as health records, connected devices, patient privacy rules, healthcare system regulations, payer and care network structures, population health and patient pathways, disease and epidemiology knowledge, the company has a major competitive edge over other blockchain and tech companies who have limited experience and relationships to the healthcare system and its complex regulation, let alone in other countries where systems and regulations differ from their home country.

Combining our experience at IBM, IQVIA, and Nokia Healthcare, Embleema’s leadership team also has a proven track record in building scalable, highly available and manageable SaaS systems on a global footprint. Embleema can significantly contribute to the Blockchain community by adding those missing features in the current Blockchain stacks as part of its leadership role at the Linux Foundation Hyperledger Healthcare Working Group.

As a significant milestone, Embleema is the first company to publicly release a working blockchain EMR product in the world last July 2018 and by proving with the release of a product its strategic, functional and technical abilities, Embleema is well positioned to materialize the Embleema Health Blockchain Version 2.