Digital Health Regulation

Life Sciences and Healthcare Digital Businesses

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Brazilian health system overview

1. Brazilian National Sanitary Agency

2. Research Ethics Committees

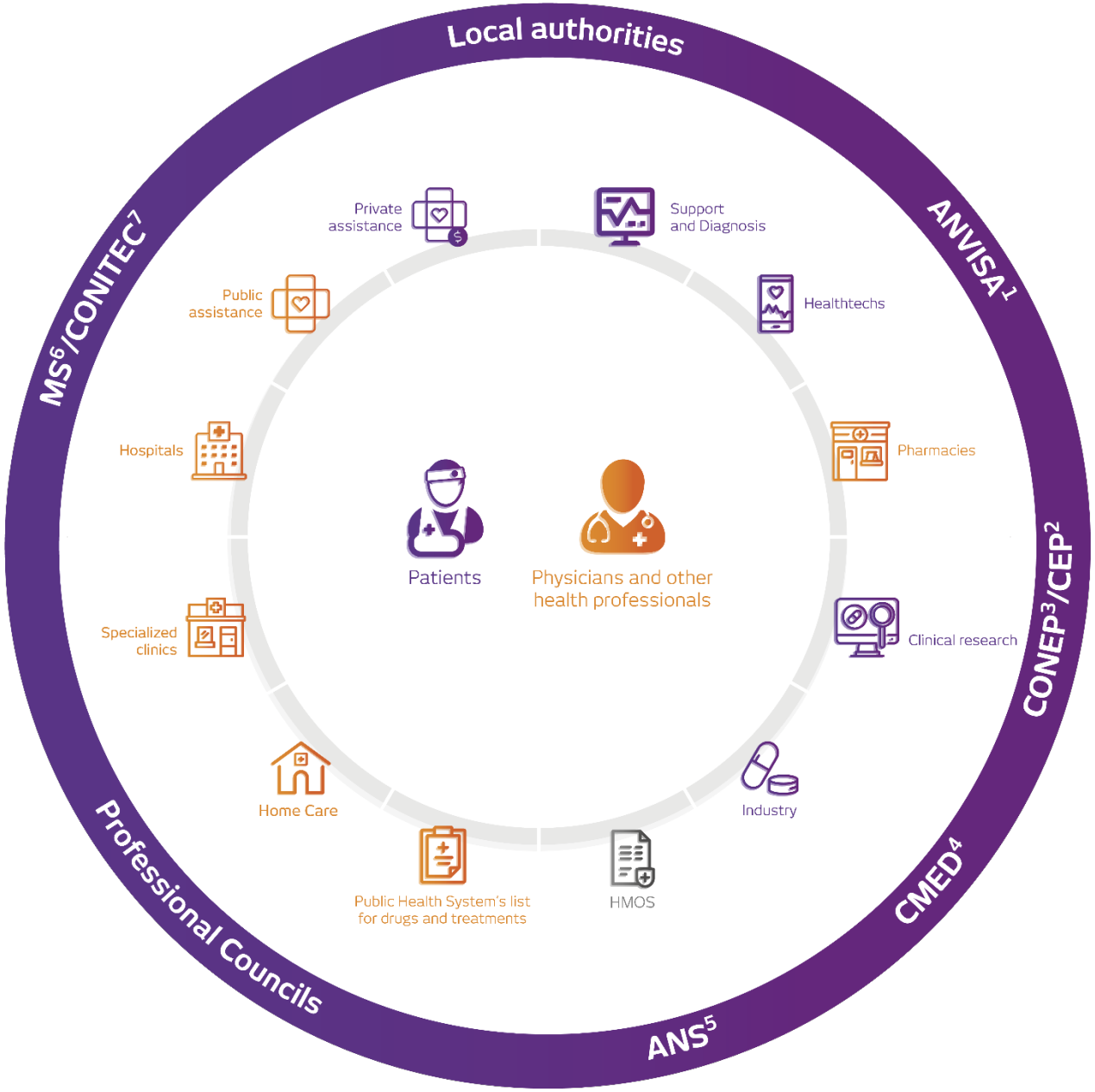
3. National Research Ethics Commission

4. Drug Market Regulatory Board

5. National Agency for Health Plans

6. Ministry of health/SUS

7. National Commission for Incorporation of Health Technologies



Brazilian health sector features

- Health as a right (**JUDICIALIZATION**):
  (i) Private health coverage and contracts;
  (ii) Expensive and/or off label treatments, including for rare diseases;
  (iii) Medical malpractice.
- Intense regulation (life-threatening and disproportionality in **doctor-patient relationships**);
- **Requirement of informed** consent for clinical research, treatments, interventions, and personal health data;
- Recent end of legal restriction for foreign **investment in private health assistance** (2016);
- Consolidation strategies (vertical and horizontal);
- Sale of traditional business units to invest in disruptive solutions;
- Multidisciplinary approach;
- Change in remuneration models (ongoing push toward value-based care and reducing costs in the sector).

Regulations that influence the relationship between technology and health

- Brazilian Internet Act and correspondent decree
- National Policy for Technological Innovation in Health
- Law on Access to Public Information
- Law on the use of Electronic Health Records
- Brazilian General Data Protection Law (LGPD)
- Federal Council of Medicine Resolutions on Telemedicine

Other regulations

- Medical Code of Ethics
- Regulations of other Professional Councils
- Regulations ANS and ANVISA
- Minimum Set of Health Data Standards
- Clinical research regulations
- Bill of Law 10,724/2018

Brazilian Internet Act

(Law No. 12,965/2014)

The Brazilian Internet Act and its regulatory decree establish the guidelines for Internet use in the country.

Rights of Internet users:

- **Inviolability of intimacy** and privacy;
- Clear and complete information about collection, use, storage, **treatment and protection of a person's personal data**;
- **Express consent to collection**, use, storage and processing of personal data, which should occur prominently from the contractual clauses;
- **Definitive deletion of personal data supplied to a particular Internet application** (when requested by the owner of the data), at the end of the relationship between the parties, subject to the chances of mandatory custody of records.

The storage and availability of personal data must consider the preservation of the intimacy, private life, honor and image of the parties directly or indirectly involved.

When collecting, storing, keeping and processing personal data, the rights to privacy, the protection of **personal data and the confidentiality of private** communications and records shall be respected.

Decree No. 8,771/2016

(Regulates the Brazilian Internet Act)

Indicates procedures for data storage and protection by connection and application providers.

Security standards to be observed when processing personal data:

- **Strict data access** control;
- Prediction of **authentication mechanisms for access to records**;
- **Creation of an access inventory**, containing information about the time of access, the duration, the identity of the person responsible for the access and the file accessed;
- **Use of record management solutions** by means and techniques that guarantee the inviolability of data (e.g. encryption).

Connection and application providers must retain as little personal data as possible, which must be deleted as soon as the purpose of its use has been achieved or if the period of time determined by legal obligation has expired.

Law No. 12,527/2011

(Law on Access to Public Information)

Establishes guidelines for the provision of public information to the population (federal, state, provincial, and municipal level).

- In providing information to the population, public authorities and entities should, among other things, protect personal information;

- Information related to intimacy, private life, honour and image shall have restricted access and may be disclosed with the express consent of the person to whom they relate.

Consent to disclosure and access by third parties will not be required:

- When the information is **necessary** for the prevention and medical diagnosis;

- When the person is **physically or legally incapacitated**;

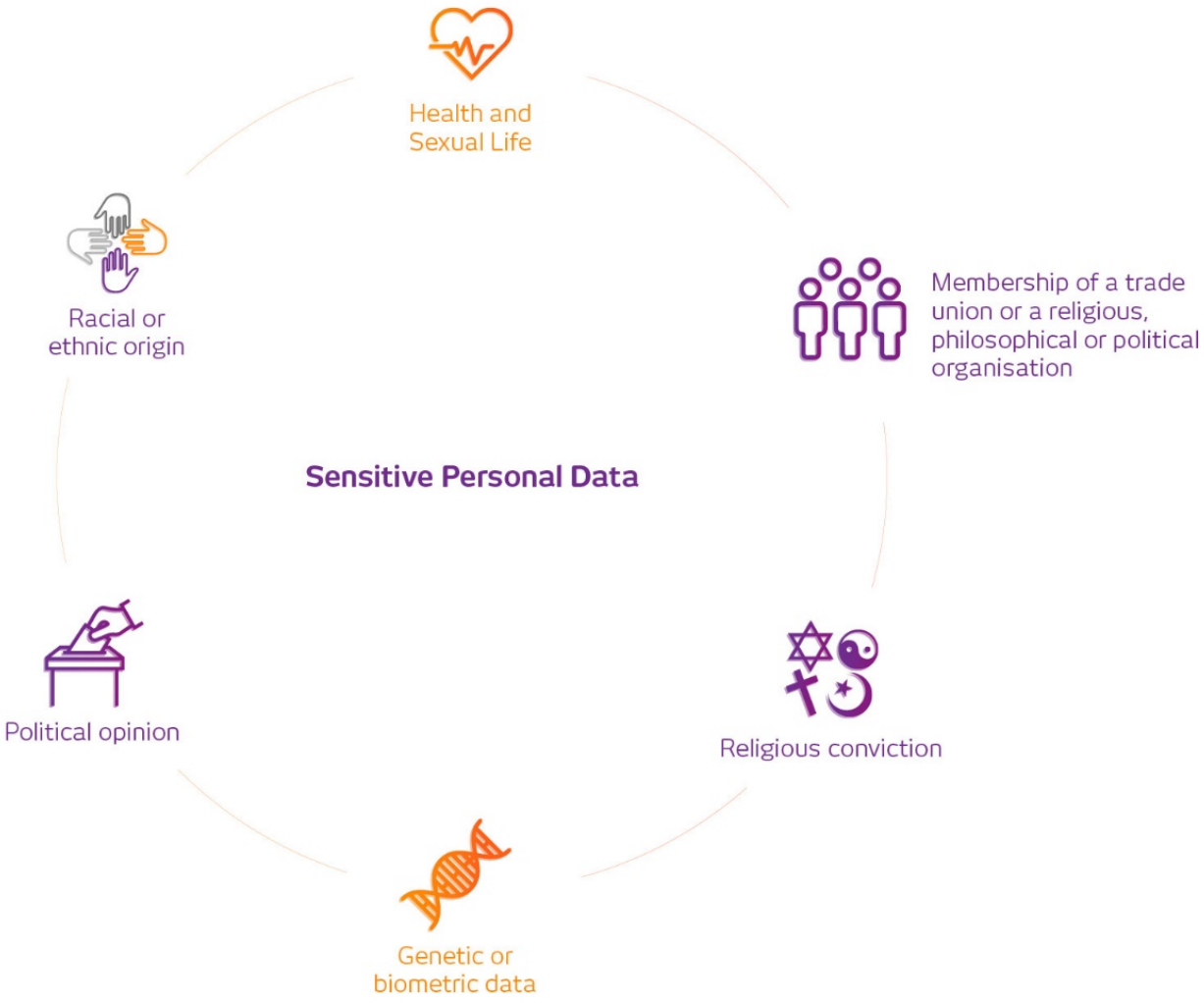
- For **exclusive** use of **medical treatment**.

Brazilian General Data Protection Law (LGPD)

(Law No. 13,709/2018 amended by Provisional Measure No. 869/2018)

Expectation of **complementary regulation by the Ministry of Health/MS and National Data Protection Authority/ANPD.**

Sensitive Data Concept



Legal Bases for Sensitive Data Approach

(Law No. 13,709/2018 amended by Provisional Measure No. 869/2018)

Specific and prominent consent

Regular exercise of rights, including in contract

Protection of Life

Regular exercise of rights in judicial, administrative or arbitral proceedings

Research and Study

Legal or regulatory obligation

Protection of the Right to Health

Fraud Prevention

Important Aspects of the Brazilian General Data Protection Law (LGPD) for the Health Sector

(Amendments by Provisional Measure No. 869/2018)

Protection of the Right to Health: legal basis after Provisional Measure No. 869/2018)

Art. 11, II, f) Health protection, **exclusively, in procedures performed by health professionals, health services or health authority**.

Health Data Sharing

Art. 11, § 4º Communication or shared use among controllers of sensitive personal data related to health in order to obtain economic advantage is prohibited, except in cases related to the provision of health services, pharmaceutical assistance and health care, **provided that it is observed § 5 of this article**, including the auxiliary services of diagnosis and therapy, **for the benefit of the interests of data holder, and to allow**:

i. **Data portability** when requested by the data holder; or

ii. **Financial and administrative transactions** resulting from the use and provision of services that this paragraph is about.

Sensitive Health Data Treatment for Risk Selection

Art. 11, § 5º HMOs are prohibited from treating health data for the practice of risk selection in the hiring of any modality, as well as in the hiring and exclusion of beneficiaries.

Materialization of the **principle of non discrimination**.

ANS Regulations

Law No. 9,656/1998 establishes that no one may be prevented from participating in private health care plans on the grounds of age or condition of a person with a disability.

ANS 27/2015 Normative Precedent:

- **The practice of risk selection by health plan operators is prohibited** in the contracting of any type of private health care plan;
- In the contracting of **collective corporate or collective plans by adhesion, the prohibition** applies both to the entire group and to one or some of its members;
- The prohibition applies both to **hiring and exclusion of beneficiaries**.

It configures infraction to the ANS regulations:

To disclose or provide to third parties not involved in the provision of assistance services, information on the health conditions of beneficiaries, containing identification data, without their express consent, except in cases authorized by legislation

- **Penalty:** fine of BRL 50,000.00. In the event of recurrence, the suspension of the exercise of office for 90 (ninety) days will be applied (cumulative to the fine).

Peculiarities of Research Entities

Definition: Direct or indirect public administration body or entity or private non-profit legal entity legally constituted under Brazilian laws, with headquarters and jurisdiction in the country, which includes in its institutional mission or in its social or statutory goal the basic or applied research of historical, scientific, technological or statistical nature.

The processing of sensitive personal data may be carried out **for the purpose of studies by research bodies**, with the anonymisation of sensitive personal data being guaranteed whenever possible.

> **Disclosure of search results may not reveal personal data and may not be transferred to third parties.**

Public Health Studies

In the absence of normative definition, research organizations may have access to personal databases for the purpose of conducting studies and research, according to security practices provided for in specific regulations and that include, whenever possible, the **anonymization or pseudonymization of data**, as well as consider the appropriate ethical standards related to studies and research.

Treatment through which a data loses the **direct or indirect** possibility of association, if not by the use of additional information maintained separately by the controller in a controlled and safe environment.

National Policy for Technological Innovation in Health (PNITS)

(Decree No. 9,245/2017)

Regulates hiring and acquisitions that involve strategic products and services for the Public Health System (SUS).

GOALS

- Promote the technological and economic sustainability of SUS by increasing its productive and innovation capacity;
- Stimulate innovation and partnerships between public administration and private entities, aiming at the transfer, internalization, incorporation, development and qualification of health technologies;
- Promote research, development and manufacturing of strategic products and services for the Public Health System (SUS);
- Reduce the country's external dependence and productive and technological vulnerability;
- Rationalize spending on health and induce scientific, technological and industrial development, with a view to the sustainability of the Public Health System (SUS), expansion of access to health and consolidation of the Industrial Complex of Health (CIS) in Brazil.

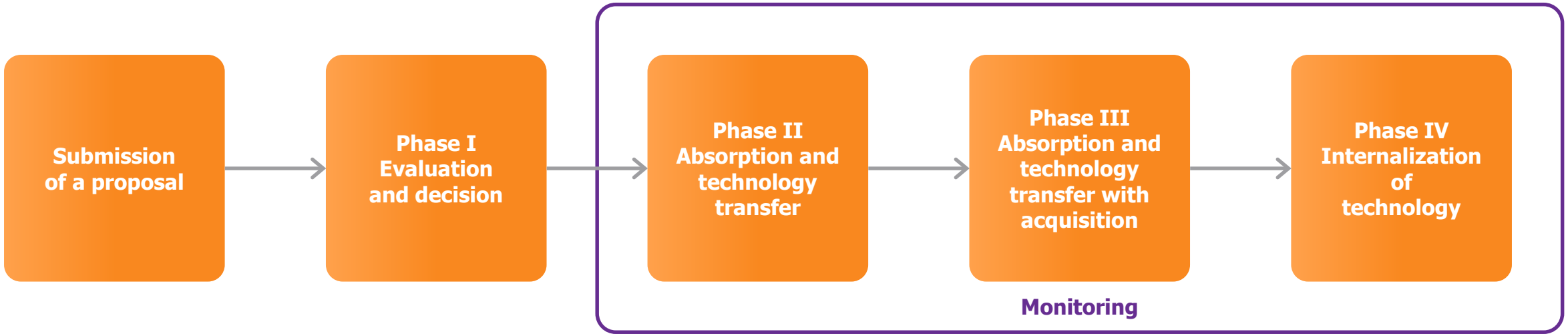
Public Hearing 71/2018 discussed complementary norms for the implementation of PNITS.

Strategic tools to stimulate innovation

PDPs

Productive Development Partnerships (PDPs) – entered into between public institutions and private entities for the development, transfer and absorption of technology, production, **productive and technological training** of products considered necessary for actions of promotion, prevention and recovery of health, with centralized acquisitions by **Ministry of health (Strategic Products for the Public Health System - SUS)**.

Establishes prices and deadlines contractually.



Strategic tools to stimulate innovation

ETECs

Technological Orders in the Health Area (ETECs) – Hiring of a Science and Technology Institution (ICT), private non profit entities or companies, to carry out **research, development and innovation activities** that involve **technological risk**, to solve a specific technical problem or to obtain a product, service or innovative process in the health area.

MECs

Compensation Measures in the Health Area (MECs) – Application of industrial, commercial or technological compensation measures, as provided for in the Bidding Law, aiming at technological development and training – observing the list of strategic products and services for the Public Health System (SUS).

It will depend on a previous process that guarantees the **competitiveness, transparency and equality of the competition**.

Law on the use of Electronic Health Records

(Law No. 13,787/2018)

Provides on the digitalization and use of computerized systems for the safekeeping, storage and handling of the patient's medical record.

- It shall ensure the **integrity, authenticity and confidentiality** of the digital document;
- **Same evidential value** as the original document;
- **The original documents may be destroyed** after digitization and analysis by the review committee of medical records;
- Storage media should **protect them from unauthorized access**, use, alteration, reproduction and destruction.

After 20 years from the last registration, paper-based medical records and scanned records can be **deleted or returned** to the patient.

Software as medical device ("SaMD")

(ANVISA Resolution No 185/2001 and ANVISA Technical Note 04/2012)

Technical regulation on registration, update and or cancelation of marketing authorizations for health products, including software.

- Defines health products as the product envisaged for medical, dental or laboratory application, intended for prevention, diagnosis, treatment, rehabilitation of a disease/condition or contraception purposes. Such category encompasses SaMD.
- These products are subject to the obtainment of a previous marketing authorization with ANVISA before commercialization, as well as specific quality, safety and efficacy requirements.
- Public Consultation No 730/2019 (expired) – proposed rule expected to provide granularity on the classification and requirements for SaMD.

Contributions to IMDRF Guides disclosed by ANVISA open until June 26, 2020

Ministry of Health's Digital Health Initiative (E-Health)

Global strategy on digital health

WHO is leading the development of a global strategy on digital health in consultation with Member States and key stakeholders. The Strategy aims to accelerate adoption of digital health, strengthen commitment and capacity for action and align partnerships, innovation and research towards Health for All.

The strategy is ready and accessible for public consultation until 30 April 2019.

– Consultation on the Global Strategy on Digital Health

World Health Organization

WHO Guideline: recommendations on digital interventions for health system strengthening

Digital health has historically been characterized by implementations rolled out in the absence of a careful examination of the evidence base on benefits and harms. This guideline presents recommendations based on a critical evaluation of the evidence on emerging digital health (specifically mobile health) interventions that are contributing to health system improvements, based on an assessment of their benefits, harms, acceptability, feasibility, resource use and equity considerations.

WHO Guideline: recommendations on digital interventions for health system strengthening

Global Strategy on Digital Health 2020-2024

Aim to computerize the Public Health System (SUS) by 2020 by building and consolidating an eHealth platform grounded in strategies, policies, practices, governance and investment mechanisms, capacity building of human resources, infrastructure, and technologies.

Ministry of Health's Digital Health Initiative (E-Health)

- Based on guidelines of the World Health Organization ("WHO"), **it aims to computerize the Public Health System (SUS) by 2020**, through a platform based on strategies, policies, practices, governance and investment mechanisms, capacity building of human resources, infrastructure, and technologies;
- **It seeks to optimize resources** by using digital technologies to promote/amplify access to health and improve the patient experience;
- **Computerization of the Public Health System (SUS)** and implementation of Electronic Health Record (today there are about 43,000 public clinics (UBS) in the country and only 21,000 are computerized);
- More efficient public policies and processes;
- **Interoperability standards and health information** for health information systems within the Unified Health System;
- Accreditation Notice for computerization of public clinics (UBS) (currently suspended).

Telemedicine Act (Law No. 13,989/2020)

Authorizes the use of telemedicine during the crisis caused by coronavirus (SARS-COV-2).

- Defines telemedicine as the practice of medicine through technologies for assistance, research, disease and injury prevention, and promotion of health.

- **Medical obligation** to inform the patient all the limitations inherent in the use of telemedicine, given the impossibility of physical examination during the video consultation..

- **Vetos** concerning the legislation that had been approved by the National Congress:
  i. Exclusion of the provision on the validity of medical prescriptions with electronic or digitized signature, under the argument that the measure would generate health risk to the population since it equates one signature that uses cryptography and has legal validity to another that is easily tampered with.
  ii. Exclusion of the provision on the jurisdiction of the Brazilian Federal Council of Medicine to regulate telemedicine after the crisis period, which according to the veto should be regulated by law.

Telemedicine Ordinance

(Ordinance No. 467/2020 of the Ministry of Health)

Regulates Telemedicine actions exceptionally and temporarily, such as the measures of the Public Health Emergency of International Concern resulting from the COVID-19 pandemic.

1.

Remote interactions can include pre-clinical care, support, consultation, monitoring and diagnosis through information and communication technology, in the scope of SUS (the publicly funded healthcare system of Brazil), as well as in supplemental and private health care.

2.

Virtual consultations must be registered in a clinical record, including:

A. the necessary clinical data for a proper handling of the case, being completed at each contact with the patient;

B. date, time, information and communication technology used for the consultation; and

C. the physician's Regional Council of Medicine registration number and its state of origin.

3.

Issuance of electronic medical certificates and/or prescriptions are expressly allowed.

Medical Code of Ethics

(Federal Council of Medicine Resolution No. 2,217/2018)

> **Establishes the norms and guidelines for medical practice (including teaching, research and administration of health services).**

Duty of secrecy:

The physician must keep secrecy in relation to the information he or she possesses as a result of his or her medical performance, unless there is a fair reason, legal duty or consent to disclosure of the fact, in writing, of the patient.

It is not allowed to prescribe treatments and/or procedures without direct examination of the patient, except in cases of urgency or emergency and proven impossibility to perform it. It is also not allowed to consult, diagnose or prescribe by any means of mass communication.

Although it provides for remote medical care in the form of telemedicine, the Code is limited to indicating that the regulation of such matter will occur through specific regulation of the Federal Council of Medicine.

Telemedicine CFM Ordinance

(Federal Council of Medicine Resolution No. 1,643/2002 - currently valid)

Defines and establishes rules for Telemedicine.

- **Definition:** Exercise of Medicine through the use of interactive **methodologies of audiovisual communication and data**, with the objective of assistance, education and research in Health;
- **Requirements:** technological infrastructure that obeys the Federal Council of Medicine rules on safekeeping, handling, data transmission, confidentiality, privacy, and guarantee of professional secrecy;
- The physician who issues the report at a distance can only provide diagnostic and therapeutic support in case of **emergency or when the doctor responsible request**;
- **Federal Council of Medicine Opinion 50/2016:** The use of WhatsApp and similar platforms is permitted for **communication between physicians and their patients**, as well as between physicians and physicians, on a private basis, with the provision that all past information is absolutely confidential. Physicians who participate in groups are personally responsible for the information, opinions, words and media they make available in their discussions.

The understandings of the Brazilian National Agency of Supplemental Health (ANS) on Telehealth

- **Technical Note No. 7/2020**: establishes that the healthcare provided through remote communication is a mandatory procedure that is already included in the List of Policies and Procedures in Healthcare (Rol de Procedimentos e Eventos em Saúde) since it does not correspond to a new procedure, but rather to a non-face-to-face medical consultation.

- **Technical Note No. 3/2020**: states that in order for the consultation to be held via telehealth during the Covid-19 crisis, operators and health service providers must agree mutually and in advance, by any means (e.g. Email), indicating:

i. The description of services that can be provided via telehealth;

ii. The prices to be paid for the services provided in this type of consultation;

iii. The procedures to be followed for billing and payment of these services; and

iv. The procedures that will require prior authorization to carry out this type of consultation.

- In addition, the ANS also adapted the Standard of Information Exchange in Supplemental Health (TISS), with the inclusion of the new type of consultation: telehealth.

Telehealth Regulations

By the Federal Council of Nursing (COFEN):

According to the COFEN Resolution No. 634/2020, the electronic means used in teleconsultation should be sufficient to safeguard, store, and preserve the electronic interaction between nurse and patient. The electronic/digital records of the patient's consultation should include:

i. Identification of the nurse;

ii. Consent form of the patient, or of her/his legal representative, which can be electronic (Email, communication apps or by telephone);

iii. Identification and data of patient;

iv. Record of date and start and finish time of consultation;

v. Medical record of the patient;

vi. Clinical observation;

vii. Nursing diagnosis;

viii. Nursing care plan; and

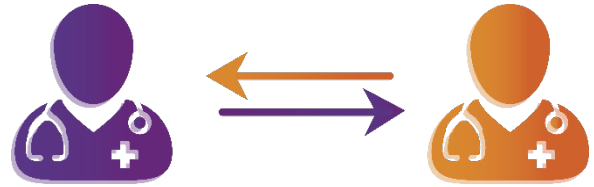
ix. Nursing assessment and/or referrals.

By the Federal Council of Nutrition (CFN):

According to the CFN Resolution No. 646/2020, nutritional assistance is permitted by remote means until August 31, 2020.

Telehealth in the Public Health System (SUS)

Aim of complementing the basic care service of the Public Health System (SUS), providing the professionals from the Public Health System (SUS) with the following services:



i. **Teleconsulting:** registered consultation among professionals and managers of the health area, by means of two-way telecommunication instruments to clarify doubts about clinical procedures and health actions in a synchronous manner (in real time) or asynchronous (off-line messaging);

ii. **Telediagnosis:** autonomous service that uses information and communication technologies to support diagnosis across geographical and temporal distances;

iii. **Second Formative Opinion**: systematized answer, based on a bibliographic review of the Virtual Health Library - Primary Health Care (BVS-APS), in the best scientific and clinical evidence on questions originated from teleconsultancies, selected based on criteria of relevance and relevance in relation to the Public Health System (SUS) guidelines; and

iv. **Tele-education:** conferences, classes and courses, taught through the use of information and communication technologies.

Telehealth within the scope of urgency and emergency care

- **It is a specific task of the Emergency Medical Regulation Centres** to identify, qualify, and classify distress calls from health units, judge their relevance and exercise telemedicine whenever necessary;

- **Technical competence** of the physician who regulates urgencies and emergencies and recognizes the exercise of telemedicine, as well as the continuous recording of communications, **the correct completion of medical regulation forms**, medical and nursing care forms and the monitoring of institutional protocols;

- **Responsibilities of the nurse professional and of the nursing assistant working in mobile prehospital service in the emergency room:** provides for the execution of medical prescriptions by telemedicine and the supply of medicines orally and parenterally, by prescription of the regulating physician by telemedicine.

Challenges for Digital Health in Brazil

LEGAL UNCERTAINTY

- Absence of a specific regulatory framework;
- Revocation of norms;
- Several authorities regulating the sector, including through the judiciary.

TRANSPARENCY AND INCENTIVES

- Relations between players and stakeholders in the sector;
- Engagement of professionals and patients;
- Changing behaviors and routines for adherence to new technologies;
- Financial and technological resources vs. cost-benefit;
- Scientific validation vs. Overclaiming;
- Alternatives that enable the sustainability of the sector.

Challenges for Digital Health in Brazil

Need for an interoperability standard for public and private systems.

Sharing information between Electronic Health Records allows complete patient follow-up.

Improved care and preservation of patient history - more personalized.

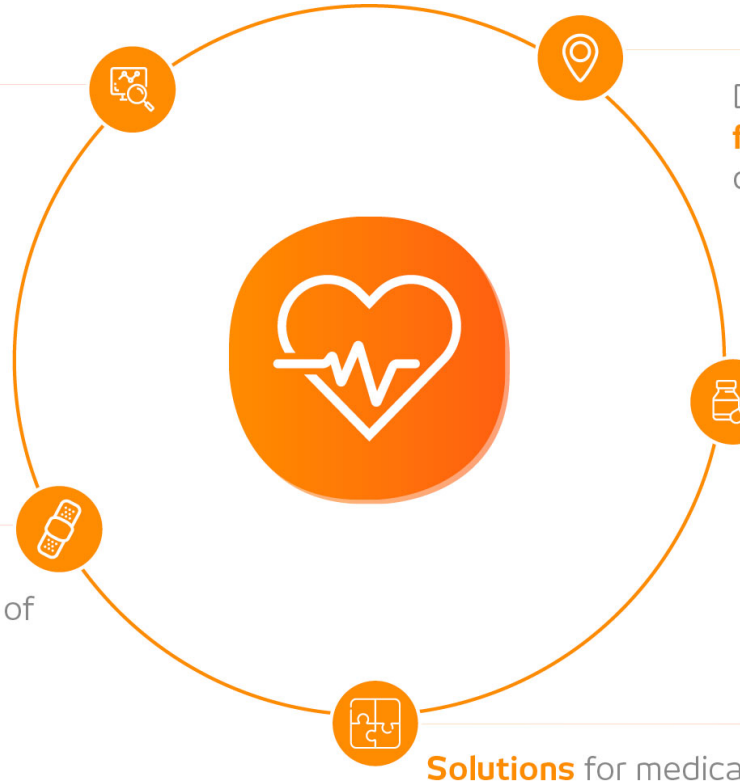
AVOIDING

- Diagnostic errors;
- Duplicity;
- Unnecessary investigation costs.

Capacity of the information to be understood:

- Compliance with **standards and terminology**;
- Reference models;
- Clinical concepts and terms;
- Quality assurance of clinical trials;
- **Comparable data**.

Internet of Medical Things (IoMT) – Innovation applied to health



Real time monitoring of elderly and debilitated patients (cardiac, apnea, etc.).

Drug tracking to **reduce forgeries** and health plan discounts.

Clinical environment screening - location of personnel, equipment, samples and drugs.

Facilitation of treatments - transmission and analysis of images, aid for ambulances.

Solutions for medical instrumentation such as analysis of remote diagnostic systems.

Internet of Medical Things (IoMT) – Innovation applied to health

Welfare - Wearables and connected clothing monitor physical exercises and vital signs.

Physicians will have **more patient data** such as the level of adherence to treatment and disease metrics.

Improved management of hospital inventory and energy consumption of connected devices.

Predictive maintenance of medical equipment - operating status and temperature.

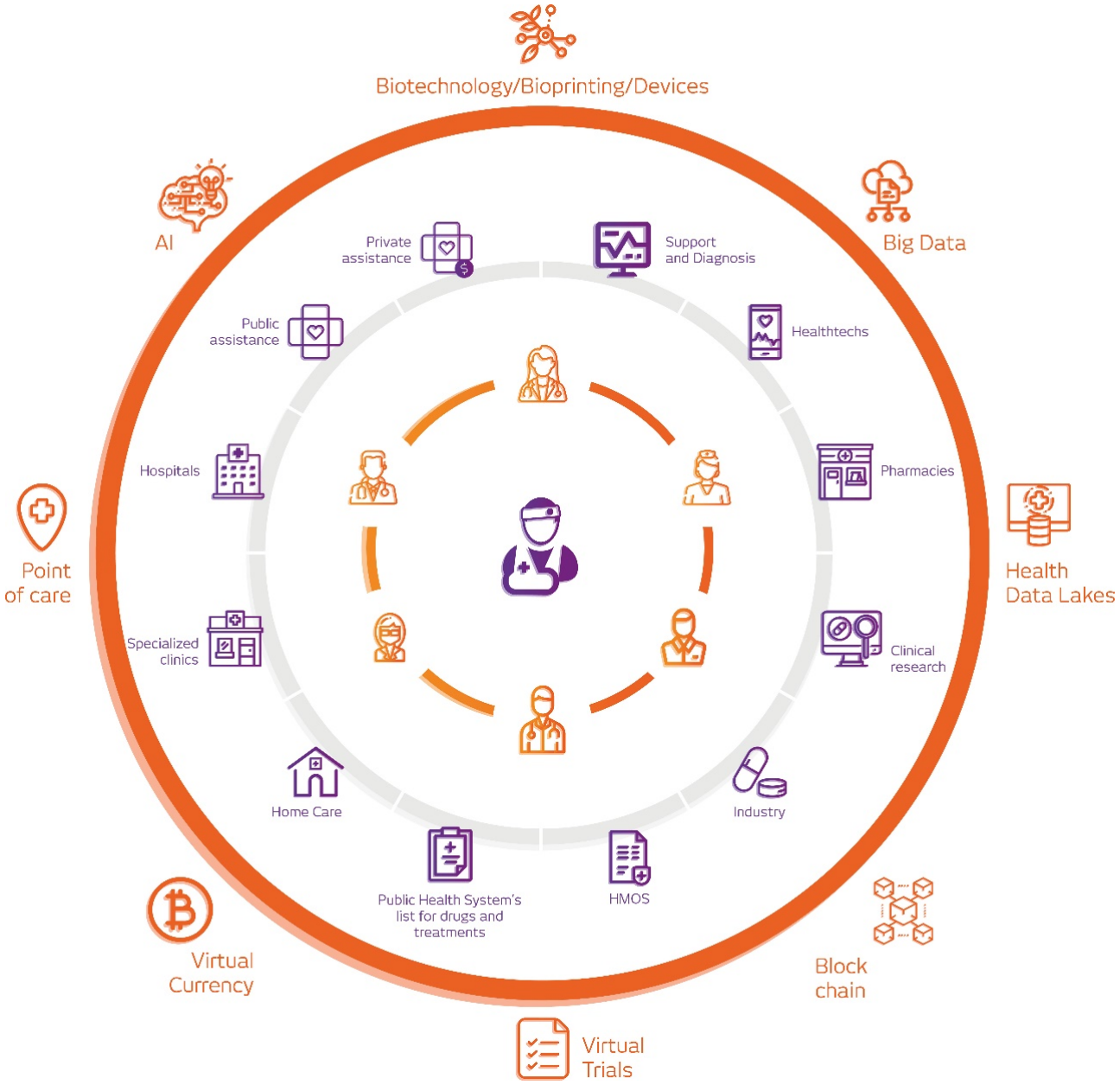
Complementation of more expensive surgical procedures (e.g. orthopaedic surgery).

Trends

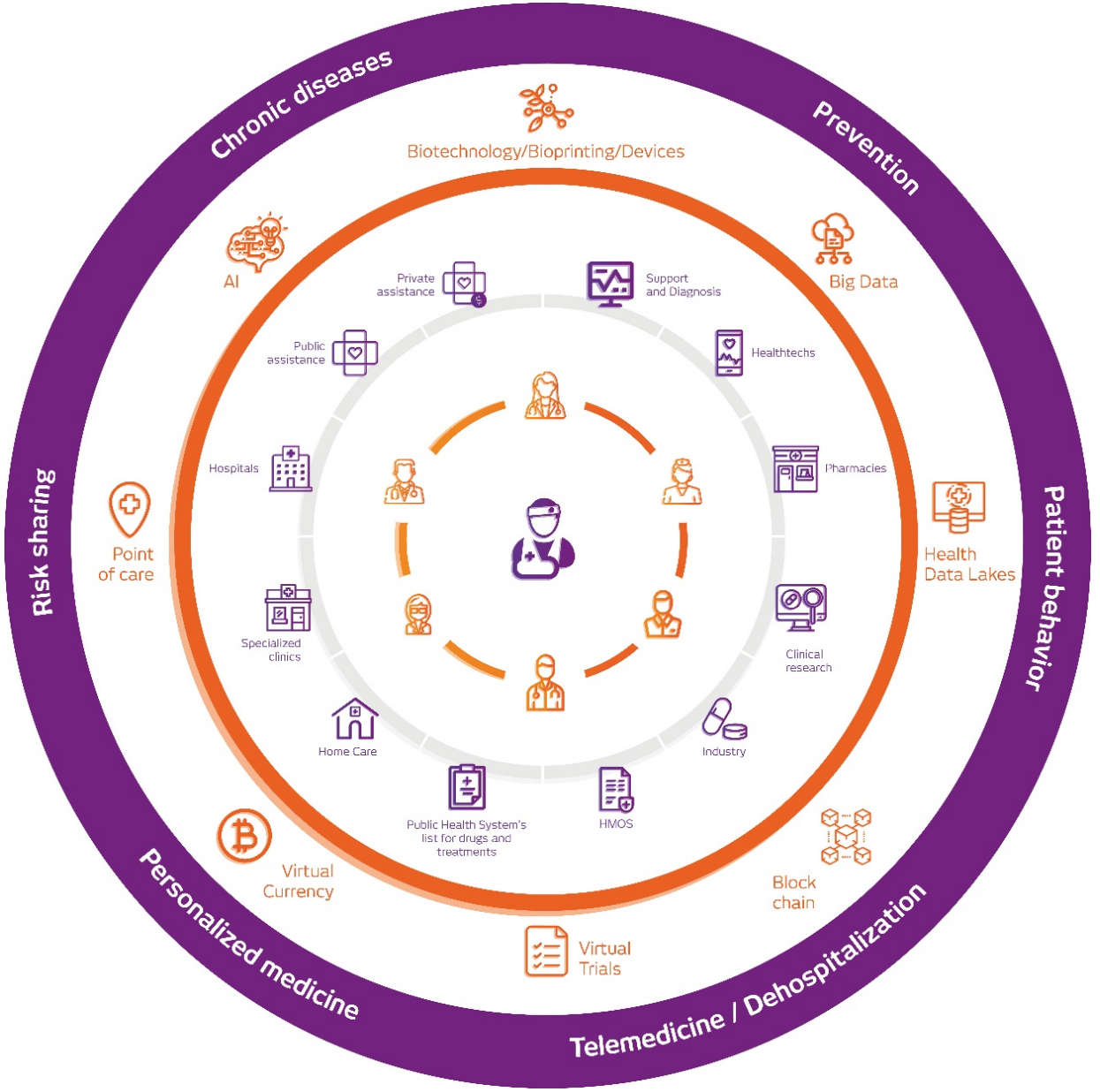
Trends


Private assistance
Support and Diagnosis
Public assistance
Healthtechs
Hospitals
Pharmacies
Specialized clinics
Clinical research
Home Care
Industry
Public Health System's list for drugs and treatments
HMOS

Trends


Biotechnology/Bioprinting/Devices
AI
Big Data
Private assistance
Support and Diagnosis
Public assistance
Healthtechs
Hospitals
Pharmacies
Point of care
Health Data Lakes
Specialized clinics
Clinical research
Home Care
Industry
Public Health System's list for drugs and treatments
HMOS
Virtual Currency
Block chain
Virtual Trials

Trends


Chronic diseases
Prevention
Patient behavior
Telemedicine / Dehospitalization
Personalized medicine
Risk sharing
Biotechnology/Bioprinting/Devices
AI
Big Data
Private assistance
Support and Diagnosis
Public assistance
Healthtechs
Hospitals
Pharmacies
Point of care
Health Data Lakes
Specialized clinics
Clinical research
Home Care
Industry
Public Health System's list for drugs and treatments
HMOS
Virtual Currency
Block chain
Virtual Trials

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