

**Bial**

---

Keeping  
life in  
mind.



# Code of Ethics and Conduct

March 2019

# INDEX

<b>MESSAGE FROM THE CHIEF EXECUTIVE OFFICER (CEO)</b>	<b>3</b>
<b>OUR MISSION AND OUR VALUES</b>	<b>4</b>
<b>THE CODE IN PRACTICE</b>	<b>5</b>
Objectives and scope .....	5
Commitment to the Code .....	6
Prohibition of bribery and corruption .....	6
Conflicts of interest.....	6
Communication channels.....	7
Confidentiality and non-retaliation.....	7
Consequences of violations of the Code .....	7
Additional information .....	7
<b>OUR COMMITMENT TO THE SCIENTIFIC COMMUNITY</b>	<b>8</b>
Our research and development (R&D) activity.....	8
Our products.....	9
Interaction with healthcare professionals and healthcare organisations.....	9
Promotional activities and sharing of scientific knowledge .....	10
Collaboration with regulators .....	10
<b>OUR COMMITMENT TO OFFICERS AND EMPLOYEES</b>	<b>11</b>
Protection of rights.....	11
Safety, health and well-being .....	11
Equality of treatment.....	11
Prohibition of harassment .....	12
Training.....	12
Privacy and personal data protection.....	12
<b>OUR COMMITMENT TO BUSINESS PARTNERS</b>	<b>13</b>
Competition law.....	13
Collaboration with business partners.....	13
Confidentiality and intellectual property.....	13
Use of social networking .....	14
Protection of assets .....	14
<b>OUR COMMITMENT TO SOCIETY</b>	<b>15</b>
Privacy and personal data protection.....	15
Social responsibility .....	15
Environment .....	16
Contributions and political associations.....	16
Transparency .....	16
Reliability of the information.....	16
Business continuity .....	16
<b>DISCLAIMER</b>	<b>17</b>

**Bial**

Keeping life  
in mind.

## MESSAGE FROM THE CHIEF EXECUTIVE OFFICER (CEO)

Dear Colleagues,

We are the force that drives and gives life to BIAL. Our reward is the improvement of the quality of life that we provide to people, with our medicines, all over the world.

Over time, we have grown, evolved and increased our international presence. Thus, the core values that have guided us for ninety-five years must be even more present and stronger. To work according to high ethical standards has always been part of BIAL's DNA. Only then can we earn the trust and respect of healthcare professionals, patients and of society in general, having as our pillars the quality, safety and efficacy of the products we sell.

This Code of Conduct has been created to help us remember and apply the ethical principles that govern BIAL and our relationships with all our partners, when we work together to achieve our individual and collective goals.

I emphasise that this Code of Conduct is mandatory for each and every one of us, which makes its careful reading essential.

Because the image and success of BIAL depends on every one of us and because its strength, integrity and ethics are present in our daily activities, we shall continue to work responsibly and to make a difference by providing all people who use our products with more and better life.

António Portela



**Bial**

Keeping life  
in mind.

# OUR MISSION AND OUR VALUES

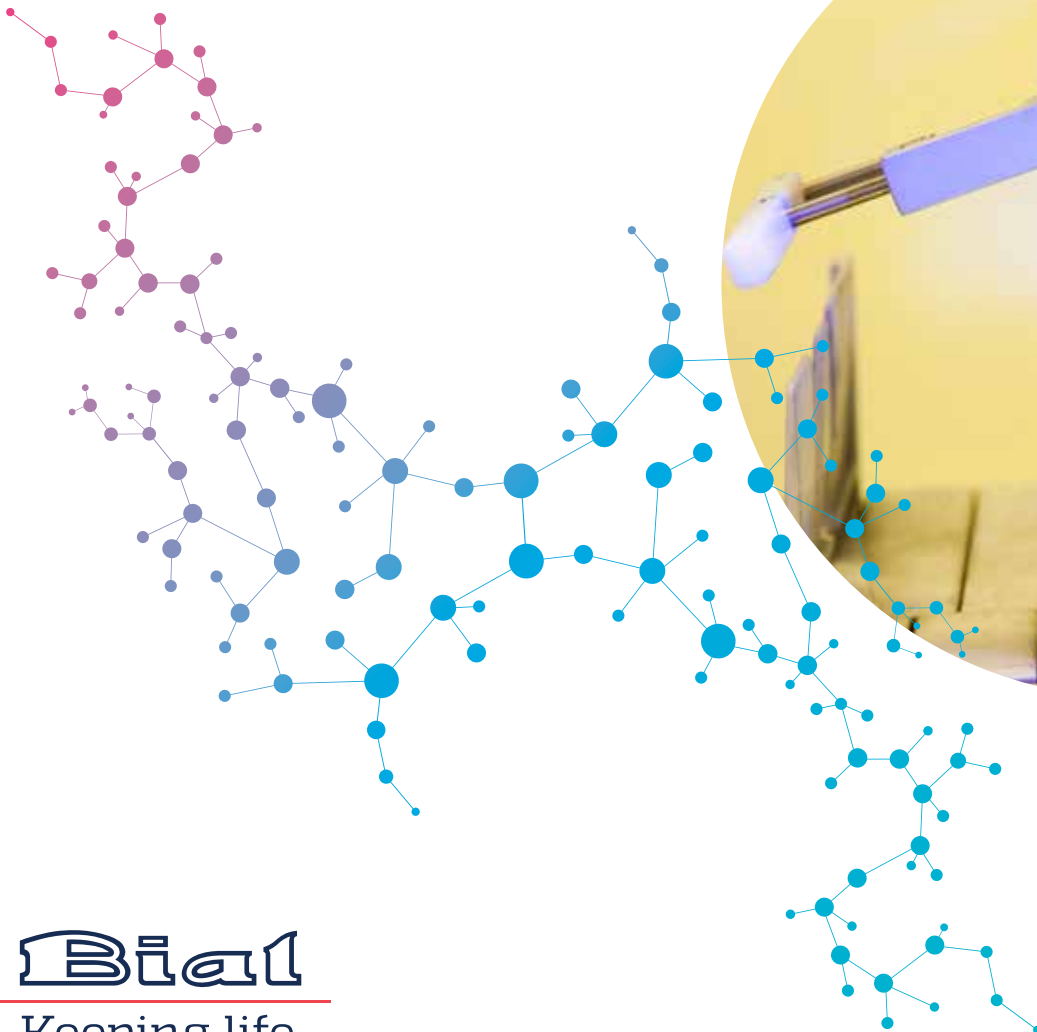
BIAL's mission is to discover, develop and provide therapeutic solutions within the area of Health.

In recent years, we have identified the strategic areas of Quality, Research and Development, and Internationalization.

Driven by our strong motivation of "Keeping life in mind", we want to provide solutions for people's Health needs by playing an active role in the global economy. We also aim to contribute to the construction of a knowledgeable society, one that is competitive, operates with utmost integrity and dynamism, and is based on scientific development and innovation.

The values that guide us reflect our identity:

- Caring for Health;
- Invest in Quality and Innovation;
- Excellence in scientific research;
- Integrity and high standards of ethics;
- Rigor, responsibility and teamwork;
- Respect for the universal values.



**Bial**

Keeping life  
in mind.



## THE CODE IN PRACTICE

### Objectives and scope

Based on the highest standards of ethics, transparency and Compliance, this Code sets forth the principles that guide our daily activity, as well as the ethical and deontological rules that must guide the behaviour of all Employees and Officers of the BIAL Group, regardless of their geographical location.

For the purposes of this Code, the following terms shall have the meaning set forth below:

- “Compliance”: complying with all Laws, Procedures and Ethical Standards.
- “Laws, Procedures and Ethical Standards”: any and all laws, directives, regulations, standards or rules – national, international or regional –, associative codes, policies, procedures and ethical, deontological and moral standards, applicable to our activities in all geographical locations where we operate.
- “Officers”: members of the corporate bodies, general managers, directors of department, heads of subdepartment, office or service, and executive officers of BIAL.
- “Employees”: all personnel having an employment or service relationship with BIAL, including temporary workers and consultants.

The principles outlined in this Code are also applicable outside the workplace for all activities where an Officer or Employee may be representing BIAL (e.g., business travel, meeting attendance, conferences, training, etc.) or be present by virtue of its relationship with BIAL.

It also applies to any other entities and/or persons contracted by or acting on behalf of BIAL.

The provisions of this Code, as a set of ethical rules that build our collective conscience as a behavioural model, shall be taken as a reference, and not as an exhaustive list, of the high moral standards of conduct that must guide us.

# Bial

Keeping life  
in mind.



## Commitment to the Code

Compliance is a fundamental value and a key asset of BIAL and as such it shall be given top priority in all our corporate activities.

All of us shall be fully committed to setting a high ethical example and shall follow all the Compliance standards of BIAL.

Each one of us is responsible for understanding and acting in accordance with all Laws, Procedures and Ethical Standards that apply to our role and job description.

We expect that our Officers, in addition to the conduct required from other Employees, are fully committed to setting a high ethical example and guiding the Employees under their supervision, acting with integrity and transparency and creating an environment of inclusion and respect. Our Officers shall also support their teams in interpreting and understanding this Code.

Attention must be paid to possible violations of our Code, which shall be reported according to the terms provided herein. Any attempts to stop someone from reporting a violation or possible violation will not be tolerated.

## Prohibition of bribery and corruption

Bribery and corruption are against BIAL's core values; they are unethical and contribute to inequality.

Therefore, we have a zero-tolerance policy regarding bribery and corruption practices.

As part of our commitment to integrity and high ethical standards in the conduct of our business activities, each and every Officer, Employee or any natural or legal person contracted by or acting on behalf of BIAL is strictly prohibited from (and from attempting to) offering, giving, soliciting, accepting or receiving any goods, services or amounts, with the intention of obtaining illegitimate economic or business benefits or advantages.

Any gifts, hospitality or entertainment must be carefully analysed in accordance with Laws, Procedures and Ethical Standards, taking into account the value, beneficiary and adequacy in general, in order to avoid any undue influence.

## Conflicts of interest

Our close relationship with third parties or influence of, or by, third parties may affect the impartiality of either party.

Thus, at each moment and in all transactions and interactions carried out in the normal course of our activity, we must carefully consider possible conflicts of interest, reporting any situations, actual or potential, to our direct manager. The direct manager shall assess the situation and make any necessary changes by appointing, if necessary, another employee to address the matter.

**Bial**

Keeping life  
in mind.

## Communication channels

Each one of us has the obligation to report the knowledge or the well-founded suspicion of behaviours in violation of this Code. For this reason, we support, encourage and protect such report as set forth herein.

### *What is the purpose?*

Internal communication channels are a way to report eventual irregularities or non-compliant behaviours which are not in accordance with the principles outlined in this Code and are intended as a way to monitor the application of the ethical and conduct standards set forth herein by all Officers and Employees.

### *To whom are the channels intended for?*

Each one of us is responsible for reporting any and every situation or suspicion of non-compliant behaviour that is not in accordance with this Code.

### *When to report?*

Report shall be made whenever we identify or have a well-founded suspicion of a violation of the principles set forth in this Code involving any Officers or Employees or third party acting on BIAL's behalf (individually or collectively).

### *How to report?*

Report can be made to (i) the direct manager, (ii) the Director of the Human Resources Department – Global, (iii) the Head of the Corporate Compliance Office, (iv) the Local Compliance Representative in your country, when applicable, or (v) the Compliance Officer of the BIAL Group.

## Confidentiality and non-retaliation

We guarantee full confidentiality regarding any reports made and respective investigation.

Each one of us is encouraged to report any situation deemed appropriate without fearing a retaliation of any kind.

Attempts to stop someone in good faith from reporting a possible violation will not be tolerated.

## Consequences of violations of the Code

Failure to comply with the Code or with the Laws, Procedures and Ethical Standards may lead to the application of penalties for BIAL (administrative, civil and criminal), causing significant business disruption and harm to BIAL's reputation, and personally for each one of us. It may lead also to disciplinary action including possible application of legally permitted penalty.

## Additional information

This Code is available to all Employees and Officers and is published on BIAL's website [www.bial.com](http://www.bial.com) and on BIAL's intranet.

It is the responsibility of each one of us to be fully familiar with this Code and to comply with the standards set forth herein.

If you need any clarification, contact your manager, the Head of the Corporate Compliance Office, the Local Compliance Representative in your country, where applicable, or the Compliance Officer of the BIAL Group.





## OUR COMMITMENT TO THE SCIENTIFIC COMMUNITY

*“Invest in Quality and Innovation; Excellence in Scientific Research”*

### Our research and development (R&D) activity

In recognition of our commitment to research, development and innovation, we are an affiliate member of the European Federation of Pharmaceutical Industries and Associations (EFPIA), the respected federation of leading research firms in the European pharmaceutical sector. We follow EFPIA guidelines and regulations in all R&D activities, as well as all relevant current International Conference on Harmonization (ICH) guidance documents and generally all Laws, Procedures and Ethical Standards regarding research, development and innovation.

All studies sponsored by us, as well as all the support activities, are conducted in strict adherence to the Laws, Procedures and Ethical Standards, including all the relevant international standards and namely:

- Ethical principles set forth in the Declaration of Helsinki (World Medical Association 2013);
- International Ethical Guidelines for Biomedical Research Involving Human Subjects issued by the Council for International Organizations of Medical Sciences (CIOMS 2016);
- Guidelines of the International Conference on Harmonization of Good Clinical Practices (ICH GCP); and
- Guidelines related to best practices for the manufacture of medicinal products (EU-GMP).

All as amended and updated, from time to time.

Our clinical research is designed, conducted and monitored to ensure the protection and privacy of the study participants in our studies and trials, as well as the integrity of the research data in compliance with applicable Laws, Procedures and Ethical Standards. We ensure that the same principles are observed and complied with when outsourcing the conduct of all or part of a clinical study to a contract research organization.

Informed and explicit consent, risk/benefit assessment, qualification of study team members and the selection of study participants conform to all CIOMS and ICH guidelines, and are consistent with the principles set forth in the Declaration of Helsinki, as well as any Laws, Procedures and Ethical Standards.

**Bial**

Keeping life  
in mind.





## Our products

We develop, manufacture, promote, distribute and commercialize medicinal products of high quality focused on the health and safety of patients.

The satisfaction of the patients, their families and caregivers, of the healthcare professionals and the scientific community, of the Employees, Officers and shareholders, and of the partners and society in general, is one of the fundamental values of our culture.

We see quality as the responsibility of each and all of us. We constantly strive to improve quality, because it is only by meeting and exceeding the expectations of healthcare professionals and patients that we will gain their trust.

These commitments will be fulfilled, by all of us, by adhering to the following principles:

- Compliance with all standards and regulatory and technical and requirements and norms that apply to our manufacturing activities (not only at production stage but also by adequately storing and handling the medicines during distribution);
- Strict compliance with all Laws, Procedures and Ethical Standards;
- Maintaining an organizational structure that ensures the highest standards of quality and respect for the environment and for health and safety;
- Continuously auditing and improving the performance of the system in order to be accepted by the community, the regulatory authorities and the market, delivering added value to BIAL and to its shareholders, Officers and Employees, healthcare professionals, patients and other interested stakeholders.

## Interaction with healthcare professionals and healthcare organisations

The interactions between the pharmaceutical industry and healthcare professionals have a profound and positive influence on the quality of patient treatment and the value of future research.

The integrity of the decision by a healthcare professional to prescribe a medicine is one of the pillars of the healthcare system and shall be always preserved.

Any interaction with a healthcare professional or a healthcare organisation must be conducted in a transparent manner and in accordance with all Laws, Procedures and Ethical Standards.

It is essential that all of us are knowledgeable about all the legal and ethical requirements that govern such interactions and ensure they are put into practice in each specific interaction.

We are committed to the principles of transparency undertaken by EFPIA and also by the national and international governments and regulatory authorities. We comply with all reporting and disclosure conditions either on each regulatory authority website or on BIAL's own institutional website.

# Bial

Keeping life  
in mind.



## Promotional activities and sharing of scientific knowledge

We commercialize and promote medicinal products worldwide and is important to ensure, directly or through our business partners, licensees, distributors and service providers that all Laws, Procedures and Ethical Standards on advertising and product promotion are complied with.

We must ensure that the information with respect to our medicinal products is provided to patients, healthcare professionals and regulators in compliance with Laws, Procedures and Ethical Standards and in a correct and timely manner, in order to allow a comprehensive information on the uses, effectiveness, safety and tolerability. Similarly, any medicines' promotional activities must be scientifically accurate, and keep within the scope of the summary of product characteristics.

BIAL's scientific departments, which include medical doctors and pharmacists, are responsible for the approval of all promotional materials before their distribution and are in charge of managing the information on BIAL's medicinal products.

## Collaboration with regulators

We operate in a highly regulated sector, so conducting our activity in accordance with Laws, Procedures and Ethical Standards required by regulators is fundamental.



# OUR COMMITMENT TO OFFICERS AND EMPLOYEES

*"Rigor, Responsibility and Teamwork"*



## Protection of rights

In accordance with our fundamental values, we are committed to respect the Universal Values and Rights, enshrined in the Universal Declaration of Human Rights and other international conventions and treaties which ensure the respect for dignity and Human Rights.

## Safety, health and well-being

It is our responsibility to ensure the right to a safe workplace, with hygienic and proper conditions. It is the responsibility of each one of us to ensure non-discrimination based on any personal characteristics, including social status, ethnicity, gender, age, religion, sexual orientation, marital status, political opinion, disability or incapacity.

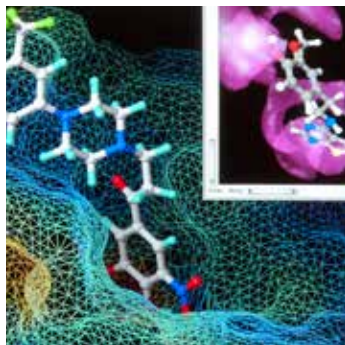
## Equality of treatment

We respect all rules to avoid unequal treatment, unfair treatment, harassment, discrimination or other unprofessional and disrespectful behaviour. Our behaviour is based on responsibility, rigor and respect for dignity and rights of persons.

Decisions taken with respect to our Officers and Employees are based on criteria such as competence, professional performance and ethical behaviour in the workplace.

# Bial

Keeping life  
in mind.



## Prohibition of harassment

Harassment is understood as an unwanted conduct, namely based on discrimination, at the time of applying for a job or during work or training, with the purpose of disturbing, offending or embarrassing the individual, affecting his/her dignity and creating an intimidating, hostile, degrading, humiliating or unstable environment.

We reject any behaviour that may constitute harassment and encourage all Officers and Employees to immediately report any harassment situations (or suspicions) which they become aware of to the Human Resources Department - Global.

The prohibition of harassment in the workplace does not mean that BIAL is precluded from exercising disciplinary power with respect to its Officers and Employees or from managing their work in the most appropriate way.

However, the exercise of coordination or leadership must be made with respect, encouraging dialogue, team spirit and respect amongst co-workers.

In the performance of their duties, all Officers and Employees must act with honesty, team spirit and respect.

## Training

We seek to develop the competences of each one of us, as a basis for professional growth, work satisfaction and commitment to quality, the environment and health and safety. We aim to reward initiative, team work and sharing of knowledge.

## Privacy and personal data protection

We are committed to complying with Laws, Procedures and Ethical Standards with respect to privacy and personal data protection, and to guarantee the rights and obligations of our Officers and Employees.

**Bial**

Keeping life  
in mind.

## OUR COMMITMENT TO BUSINESS PARTNERS

*"Integrity and High Standards of Ethics"*

### Competition law

We compete fairly and vigorously, in compliance with all competition laws and regulations.

Certain business practices, such as agreements between competitors that fix prices or the abusive use of a dominant position, may violate such laws and regulations. Because competition laws vary from country to country and are particularly complex, we shall seek advice from our legal counsels whenever our business activities might be regulated by these laws and regulations.

Failure to comply with these laws may lead to administrative, criminal and civil penalties for BIAL, and personally for each of us, with significant business disruption and harm to BIAL's reputation.

### Collaboration with business partners

In collaboration with our business partners, we are committed to act with the highest ethical standards, integrity and transparency, whether during the selection and negotiation process or during the execution of the contract.

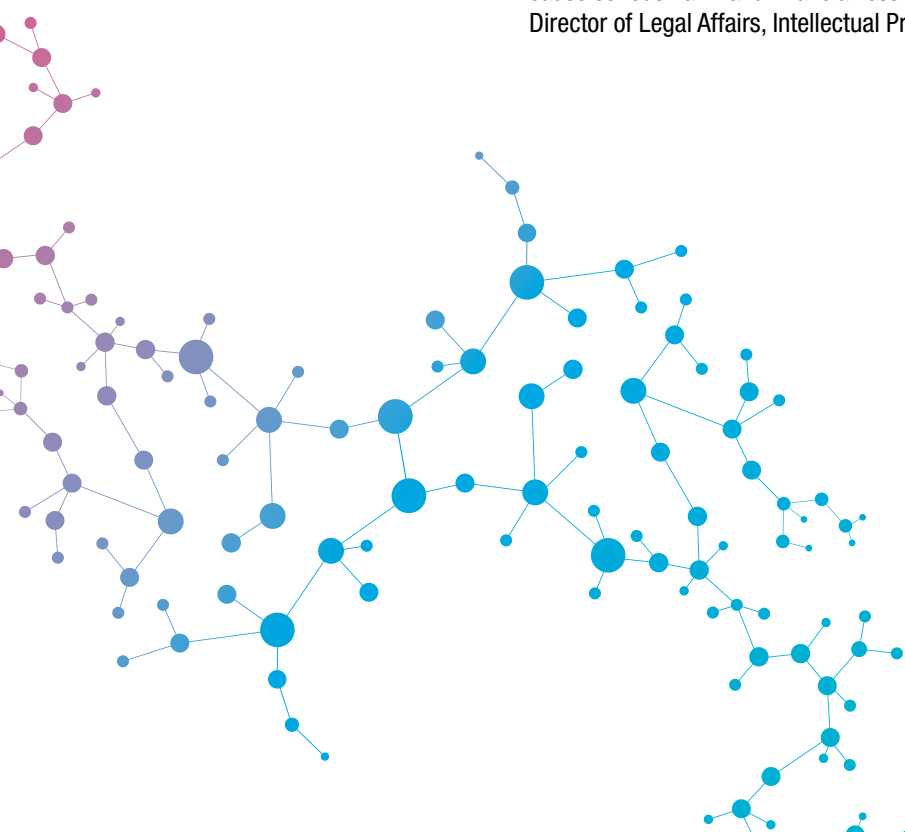
Likewise, we expect that our partners act in accordance with the same ethical, integrity and transparency standards.

### Confidentiality and intellectual property

Confidential information is an essential asset of BIAL and includes, without limitation, know-how, trade secrets, R&D and technical, regulatory, legal, financial, contractual or corporate information.

We must all protect BIAL's confidential information, which shall only be disclosed to third parties after an adequate confidentiality agreement being signed and, in any case, limited to the scope strictly necessary for the purpose.

It is the responsibility of each and every one of us to maintain and protect BIAL's assets and intellectual property to the best of our ability. Any loss, theft or improper use of these assets may cause serious harm and financial loss to BIAL and shall therefore be reported immediately to the Director of Legal Affairs, Intellectual Property and Compliance Department – Global.



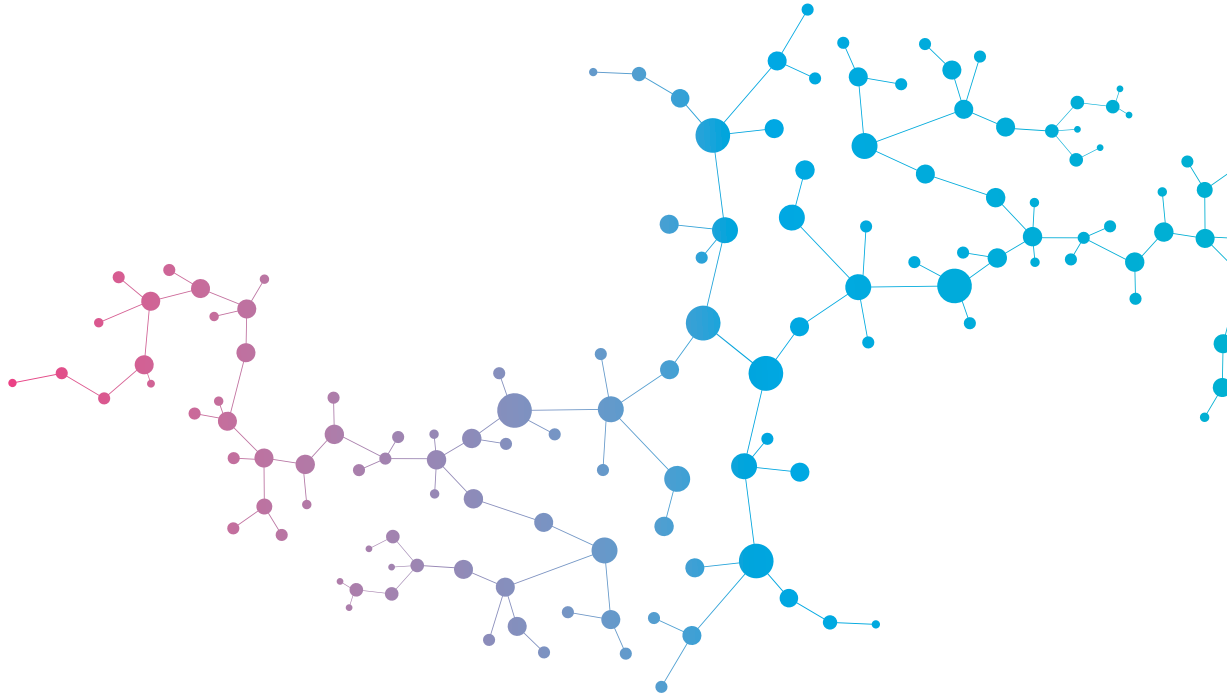


## Use of social networking

We are aware of the power and range of social networking platforms available these days. As we are aware of the potential impact that they may have to BIAL, we are committed to using social networking in an ethical and responsible way, ensuring compliance with the principles established in this Code.

## Protection of assets

In the course of our work as Officers and Employees, we have access to information related to our current, past or potential business partners, that is not available to the public in general and shall be considered relevant for investment decisions to buy or sell equity of such business partners ("insider information"). The use of insider information, as well as buying or selling equity of business partners, is strictly prohibited.



**Bial**

Keeping life  
in mind.



## OUR COMMITMENT TO SOCIETY

*“Respect for the Universal Values; Keeping Life in Mind”*

### Privacy and personal data protection

The protection of the personal data we have access to is an essential part of our mission.

In the course of our activity, we ensure that the processing of personal data is made in a lawful and transparent manner, only for the purpose for which it was originally collected and ensuring the right of access by the data subjects.

We are committed to complying with the applicable laws and regulations regarding privacy and data protection, continuously promoting internal mechanisms in order to ensure that personal data is kept secure and confidential.

### Social responsibility

We are aiming to build a world that is healthier, a world that is better for everyone. Therefore we interact with many other bodies and institutions which, like us, want to contribute to the sustained development of the planet and the construction of a fairer and more responsible society.

We are a member of the Global Compact. This is an international initiative to promote the sustainable progress of the world economy, uniting companies, governments and civil society. We are also a signatory to “Caring for Climate”, a declaration by the member companies of the Global Compact that strive to find solutions for the climate problems afflicting the planet.

We are also members of EPIS – Businessmen for Social Inclusion and we are actively engaged in supporting a number of humanitarian and social causes. We cooperate with a range of institutions on a yearly basis – hospitals, schools, universities, healthcare professional groups and patients’ associations – which work to educate, raise awareness, develop and foster the wellbeing of society in general. We actively support all these institutions, sometimes by financial support or in-kind support, always according to our values and whilst complying with our policies and procedures.

**Bial**

Keeping life  
in mind.



## Environment

We conduct our business, including manufacturing activities, in compliance with environmental laws and regulations, and in a manner that is consistent with the protection of the environment and the reduction of our ecological footprint.

## Contributions and political associations

We undertake not to make political contributions, ensuring that we conduct our activity in a transparent and independent manner regarding political questions and focusing our Mission and Values.

## Transparency

The activities of placing in circulation and/or using funds from illegal origins, consciously or negligently, such as the use of funds to finance criminal activities, constitute a crime.

We have a zero-tolerance policy regarding these behaviours; therefore, it is essential that all the transactions that we are involved in are conducted in a transparent manner and with a satisfactory knowledge of the identity of the other parties and the rationale for the transactions.

## Reliability of the information

We are committed to developing and sharing financial and non-financial information, in a complete, transparent and rigorous manner and are committed to not defrauding our business partners in the course of their activity.

## Business continuity

We believe that business continuity is essential for a responsible management and is critical to patients, Officers and Employees and other stakeholders, and we are therefore committed to do everything within our control to ensure a continuous supply of essential products and services, and to recover and restore as soon as possible the most critical processes.

We conduct a continuous risk analysis, assessing the probability and severity of the threats to which our assets are subject to, in a preventive manner, and with a continuous plan of actions aiming to mitigate the identified risks.

We are thus prepared with a continuity plan, to face any emergency or serious disruption of the business.

# Bial

Keeping life  
in mind.

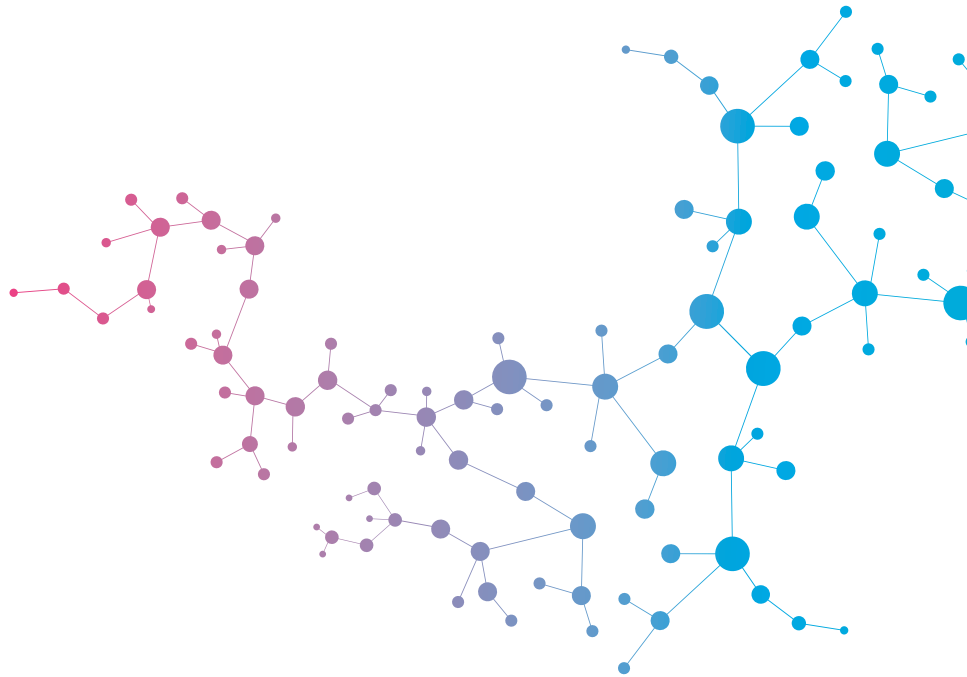


## DISCLAIMER

This Code is a guide to policies and procedures that govern the conduct of our business regardless of geography and, as such, shall be used as a reference by all of us.

However, as a guide, it does not identify, describe or detail all applicable Laws, Procedures and Ethical Standards.

This Code revokes and replaces the Code of Ethics and Conduct approved in January 2015.



**Bial**

Keeping life  
in mind.