Treatment of neurological overactive bladder with botulinum toxin and Neuromodulation with real time evolution tracking using a monitoring system of bladder behavior

1. EXECUTIVE SUMMARY OF THE PROPOSAL

In order to improve the quality of life, the project **develop a practical therapy** for the urinary incontinent neurologic patients and **refers to a method of treating the neurogenic detrusor overactivity with Botulin Toxin A (BTX-A) only, or in combination with peripheral neuromodulation**, patients being randomized for one of the two methods of treatment, with urodynamic evaluation of the results. The project proposes an original approach to the matter of neurogenic bladder and urinary incontinence that are traditionally treated with antimuscarinics with a great number of adverse events. This association, BTX-A with neuromodulation, mainly electrical peripheral neuromodulation, is often present in the medical literature and is recommended in daily practice for upper motor neuron syndrome sequelae, but, to date, no study was done for the treatment of the neurogenic overactive bladder with urinary incontinence.
According to the National Plan for Research, Development and Innovation 2007-2013, *"Applicative Research Collaborative Projects"* subprogram, one of the three main strategic objectives is to *"increase the quality of life by technical and scientific solutions to support social development and improve human condition*" the project's topic is coherent with this objective and propose the following strategy:

- *research & development activities carried out in a 4 members partnership* (1. **Gnosis Evomed SRL** – a startup SME , currently developing an innovative diagnose and treatment center for urinary incontinence -, 2.**East European Center for Integrated Applicative Research -CEECAI** - an interdisciplinary research organization offering both necessay resources, high tech R&D infrastructure and high specialised research team able to support development of new devices for medical use, 3. **University Emergency Hospital Bucharest** -*Neurology research unit* - holding an extensive patients database and able to test the new resulted medical devices - and 4. **National Institute for Rehabilitation, Physical Medicine and Balneal-climatology -**able to provide the know-how on neuromodulation and to teach the patients/caretakers to use themselves the neuromodulation devices and personal uroflowmeters resulted from project-).
- *an encouraged growth of private R&D co-financing costs* in the field of medical protocols and resulted electronic devices trough the participation of Gnosis Evomed which will be the first provider of these innovative treatment medical services;
- *the continuous development of the institutional capabilities and high level human resources skills* trough hightech equipment accessing by researchers, both goals being **dedicated to the applicative interdisciplinary research and the innovative technologies development in Romania.**

The **expected results** of the project are:

- A study showing proven differences in efficacy (suppressing symptoms, duration of efficacy, adverse events due to toxin spread, QOL) for the two types of treatment protocols, BTX-A alone and BTX-A with peripheral nerve neuromodulation.
- A comparative study of the urodynamic effect -functional and clinical- of the two treatment protocols to patients with Multiple Sclerosis (MS) , Spinal Cord Injury (SCI) and with urinary incontinence.
- Functional experimental models of networking personal uroflowmeters connected to a server /PC controlled by the doctor.

The **end product** of the project is a new medical protocol, offering the most efficient way to treat neurogenic bladder with urinary incontinence. The protocol will contain information regarding optimal dosage and methodology regarding the practice in order to improve the quality of life of individuals with neurogenic overactive bladder and diminish costs for health care in these cases.