

SPOT LIGHT

How Can Nasal Drug Delivery Devices Increase Patient Compliance and Safety?

The intranasal route of administration is used for a variety of drugs and is an attractive option for locally acting drugs, as well as systemic acting drugs, with a rapid onset of action and ease of use

The majority of treatments via the nasal route are self-administered; therefore, nasal delivery systems can have a positive impact on compliance. Advances in devices and electronics are also opening up the possibility of adding features to increase patient adherence, such as a 'do not forget me' function with reminders through an app. For potent drugs, electronics improve patient safety while preventing the device from delivering multiple doses in a row, avoiding any overdosing.

Advancia®: The Advanced Level of Patient Adherence

Current challenges in treating patients who suffer from chronic diseases have encouraged pharmaceutical companies to continue innovating. The quality of life for these patients depends highly on their clinical outcomes, which are based on their adherence to the prescribed treatment. Furthermore, adherence is a key parameter that can influence the efficacy of the treatment. The device also plays an important role in proper drug intake. As with all self-administered drugs, the most critical parameter affecting device

performance is the patients themselves. A patient, most of the time untrained, relies on their personal appreciation and the instructions for use to operate the device properly. This perspective constitutes the fundamentals of human factors engineering (HFE). HFE also highlights user competence and satisfaction as equally important in ensuring patients' adherence to their treatment. Verifying both a safe and user-friendly device eventually relies on a combination of very different factors, ranging from functional to more perceptive ones, such as overall ergonomics or daily use adaptability.

The nasal spray device should help the patient accept the treatment and improve patient compliance. To achieve that, ergonomics should be applied to the nasal device design to ensure overall attractiveness and user-friendly features, such as intuitive handling, good grip, uniform delivery accuracy regardless of actuation profile, etc.

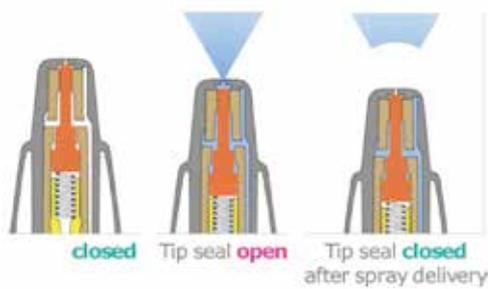
Advancia® was designed with a number of features to ensure an increased level of adherence and ease of use for improving

patient experience through different technical and design attributes.

With accurate dosing, Advancia's user-independent nasal pump guarantees a full dose delivery for every single spray. In different studies comparing Advancia to competitors, Advancia was shown to be the best performing pump, both on dose accuracy and reproducibility, independently of the user. Nemera's Advancia device was the only device to show a good correlation between *in vitro* and *in vivo* results in delivered volume and variability. Also, the Advancia platform offers a patented anti-clogging actuator, called 'closing tip'. This mechanism ensures that no contamination can enter through the actuator orifice, providing



Figure 1: Advancia®



The patented closing tip mechanism that prevents clogging

Electronics: A Step Ahead Towards Compliance

The drive towards electronic healthcare has become a well-established facet of current drug delivery device development, with various objectives, the main one being improving patient compliance. This makes total sense with the development of new drugs

delivered through the nasal cavity, with systemic or even nose-to-brain acting drugs.

We can distinguish three main drivers for electronic integration into drug delivery devices:

- Better ease of use thanks to interactions and smart guidances with the patients: electronic instructions for use (IFU), dedicated smartphone app, digital reminders, feedback on device utilisation, training, etc. (e.g., e-Advancia)
- Improvement of delivery through electromechanical systems such as wearables or locking systems for dose controlling (e.g., Safe'n'Spray)
- Data generation to enable analysis by patients, healthcare professionals, pharma companies, or payers

Nemera has recently developed two new concepts applicable to nasal drug delivery.

e-Advancia is an add-on concept offering reminders through a digital screen where IFU and dose counter can be displayed, shaking sensors, posology indication, buzzer/vibrator to find the device, geolocalisation, pump priming/de-priming alerts, and a connection with a smartphone application.



Safe'n'Spray is a smart electronic concept device to monitor drug delivery and prevent overdosing. It offers a reusable electronic locking unit (for both ecological and

economic reasons), a fingerprint sensor for patient identification, and various embedded sensors enabling a full range of data generation.

Both of these devices are connected to e-Nemera cloud system, directly (Safe'n'Spray) or through a smartphone (e-Advancia).

As data generation is becoming an important driver because of its usefulness for all drug delivery stakeholders, we decided at Nemera to connect all our electronic devices in order to offer the maximum range of services to patients, healthcare professionals, and clients.

In practice, we are developing bricks to securely send data generated by devices to our own cloud solution (directly or through a smartphone working as a gateway). These data are then stored in a system compliant with regulation, including GDPR, and organised in a way to ensure accessibility and safety. For example, data are anonymised for data mining (e.g., statistical analysis and electronic devices fleet management).

This cloud system can then send data to our clients' own systems, to third parties, or to customised front ends.

We are convinced that a turnkey solution, based on high-performing devices, electronics, and data management, is key to better serve our clients' needs.

Nemera

Nemera is a world leader in the design, development, and manufacturing of drug delivery devices for the pharma, biotechnology, and generics industries. Nemera offers a comprehensive portfolio of products and services across ophthalmology, nasal, inhalation, dermal, transdermal, and parenteral delivery. Nemera's vision is to be the most patient-centric drug delivery device company. Nemera always puts patients first, providing high-quality solutions that have a demonstrable impact on patients' health.

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protection from crystallisation and clogging issues, hence, less risk for patients of non-functional delivery systems. Also, this closing tip mechanism avoids evaporation to guarantee good prime retention. In other words, a strong prime retention helps avoid wasting the drug as there is no need for the patient to re-prime the system after each period of non-use to get their dose delivered.

To guarantee patients' safety, Nemera removed any potential contact between the formulation and metal parts of Advancia, such as the spring. The risk of introducing alien substances in the delivered dose is, therefore, minimised.

The Snap-on version with a full hygienic overcap is perfectly well-suited to today's on-the-go lifestyle, transported in a bag or a pocket. The Crimp-on version is very comfortable to use with a large and ergonomic finger flange.

Finally, as the adverse effects caused by preservatives may affect patient compliance, Nemera developed a preservative-free version among the Advancia platform. Advancia PF Snap-on relies on PureFlow®

Technology, already widely used today by preservative-free eye-droppers using the Novelia® device.

All these attributes should allow the patient to use the device properly and receive their daily dose of medication required, improving overall patient compliance.

