

## Publication Alert: Real world study of Bemfola use in Spain

Abstract | Case report/series | Retrospective study | Controlled study | Randomized, placebo-controlled study | Review article |  
Commentary | Meta-analysis | **Real world study**

### **Title: The continuum of ovarian response leading to BIRTH, a real world study of ART in Spain**

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### **SUMMARY**

BIRTH was a real-world study of 1,222 women treated in 26 assisted reproduction treatment centres throughout Spain providing experience of the use of Bemfola® for IVF/ICSI with GnRH antagonists in four distinct populations - poor responders, suboptimal responders, normal responders and oocyte donors. By studying four populations of women the BIRTH study shows a clear and related continuum of decreasing ovarian response and decreasing fertility among women.

One area of particular interest explored in this study was the use of rFSH with a product providing LH activity in what is referred to as combination, combo or mixed protocols. The study showed combination protocols are commonly used in Spain, particularly in patients over 35 years of age or among patients anticipated to have a reduced response to ovarian stimulation. However, within each BIRTH study population the implantation and pregnancy rates were lower with combination protocols than with mono therapy.

Overall, the results were consistent with the national ART results reported for Spain, hence this study provides reassurance of the clinical effectiveness of Bemfola® used in a real-world setting.

### **Key Communication Support**

- Summary of Bemfola development drawing attention to the primary importance of the exhaustive, highly sensitive physicochemical and biological activity comparability assessments required in Biosimilar drug development programs. Ultimately in 2014 Bemfola® was the first biosimilar of rFSH launched in Europe.
- Paper shows that individual patient types will have a major impact on IVF/ICSI outcomes, much more so than the FSH product used, supporting the position of the European Medicines Agency that the clinical efficacy of Biosimilar FSH is better assessed by oocyte number rather than pregnancy rate
- Illustration that Bemfola is able to meet all treatment protocol requirements including combination protocols.
- Provides evidence that questions the value of adding LH activity to IVF/ICSI stimulation protocols and further discusses this issue in the context of the literature and ESHRE guidelines on ovarian stimulation for IVF/ICSI.
- Explains that Bemfola® drug substance is now the European Follitropin Chemical Reference Substance, which may be used as reference standard to compare the quality and consistency of any rFSH drug substance prior to release of the final rFSH drug product by any manufacturer.
- Provides real world evidence of safety and efficacy of Bemfola from the national perspective of Spain.

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