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## TECHNOLOGY EVALUATION

# Evaluation of the PROPEL<sup>®</sup> mini sinus implant for the treatment of frontal sinus disease

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### ABSTRACT

**Introduction:** Propel and Propel Mini sinus implants are mometasone furoate-coated bioabsorbable stents used as an adjunct in the management of chronic rhinosinusitis after endoscopic sinus surgery. The original sinus implant was deployed in the ethmoid sinuses to provide medialization of the middle turbinate, decrease scarring and mucosal adhesions, limit polyp regrowth, and reduce mucosal inflammation. A structurally smaller version of the Propel, the Propel Mini, was developed and now has been approved for endoscopic placement in the frontal sinuses.

**Areas covered:** This evaluation will focus on the technical details of the Propel mini, previous studies documenting Propel's success in the ethmoid sinuses, and the safety and efficacy of the Propel mini implants in frontal sinus surgery.

**Expert opinion:** Devices such as the Propel and Propel Mini stents are the beginning of a trend towards medication-coated bioabsorbable implants that can be used for sinonasal disease to minimize complications or possible side effects of surgical treatment by an increase of topical drug delivery locally.

### ARTICLE HISTORY

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### KEYWORDS

Steroid eluting; implant; sinusitis; inflammation; endoscopic sinus surgery; sinus implant; Propel; Propel Mini; frontal sinusotomy; scar; polyp; chronic sinusitis

## 1. Overview of the market

The Propel device is a drug-eluting, steroid-coated bioabsorbable implant used as an adjunct in the management of chronic rhinosinusitis (CRS) after endoscopic sinus surgery (ESS). The Propel sinus implant is coated with 370 µg of mometasone furoate [1]. The Propel was the first and only FDA-approved steroid impregnated implant for the ethmoid sinus cavity following ESS to maintain patency of the nasal cavities and decrease mucosal inflammation. The Propel sinus implant was approved by the FDA in February 2011 for use in CRS and to be placed in the ethmoid sinus cavities after ESS. Propel was created by Intersect ENT Inc. (Palo Alto, CA). In November 2012, a smaller version of the Propel, the Propel Mini, was FDA approved for use in the ethmoid sinuses following ESS [2]. The Propel Mini sinus implant also contained 370 µg of mometasone furoate but was smaller and therefore can be used in patients who undergo less extensive ethmoid sinus surgery or for patients who have smaller nasal cavities.

The FDA approved the Propel Mini in March 2016 for use in the frontal sinus after frontal sinusotomy to optimize post-operative healing, limit local mucosal inflammation, and prevent scarring [3]. Propel and Propel Mini sinus implants are the only FDA-approved local delivery devices for distributing topical medications in the sinonasal cavities.

## 2. How the technology works

Propel Mini sinus implant is a biodegradable polymer in a lattice pattern that is delivered endoscopically into the frontal

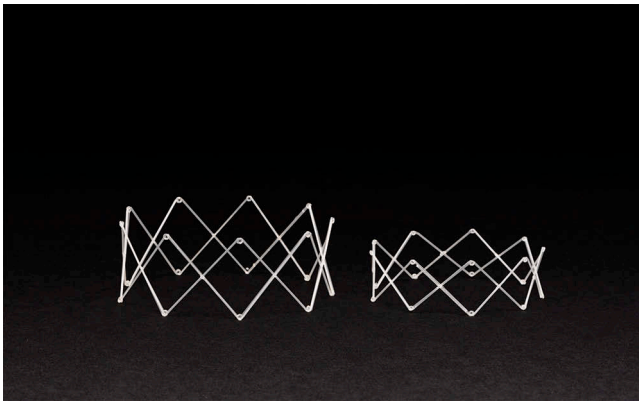
recess after a frontal sinusotomy. It delivers a local sustained release of mometasone furoate (370 µg) over an approximate 30-day period [3]. Mometasone furoate is a well-tolerated, stable molecule that coats the implant and has a high potency and low systemic bioavailability [4]. The nominal implant length of the Propel Mini is 16 mm, which is shorter than the regular Propel that is 23 mm (Figure 1). The implant is maintained in place via the spring-like mechanism of the implant and self-adheres to the sinus mucosa. The Propel Mini has to be delivered under endoscopic guidance to ensure it bridges the frontal sinus ostia to maintain postoperative patency and reduce inflammation. For the delivery of the Propel Mini, Intersect ENT has developed a crimping device, applicator with a curved clear tip, and funnel that fits on the tip of the applicator to ensure proper and easy loading as well as appropriate deployment of the sinus implant into the frontal recess.

Under surgically sterile conditions, the implant is compressed using the crimper and loaded in to the curved tip of the delivery system (Figure 2). It is key not to leave the stent in the crimped state for more than 3 min so that the Propel Mini can maintain its expansile tensile strength. Therefore, the sinus implant should not be primed and loaded for deployment until the ESS is complete and adequate hemostasis has been achieved. For insertion into the frontal sinus recess, the delivery system is oriented so the curved distal tip is angled superiorly toward the frontal sinus ostium. The distal tip of the delivery system is advanced to the area of the frontal sinus recess. Depressing the plunger while simultaneously withdrawing the applicator allows for easy deployment of the

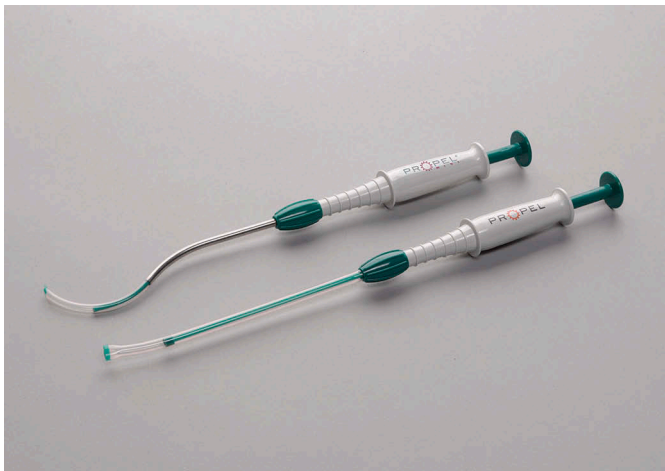
#### Article highlights

- The Propel Mini is a mometasone furoate coated implant approved for the frontal sinus in the postoperative setting.
- The Propel Mini reduces mucosal inflammation, scarring, and decreases polyp regrowth.
- The Propel sinus implants are the only FDA approved product for usage in the paranasal sinuses in the postoperative setting.
- Paranasal sinus implants are a locally, efficacious way to deliver a controlled release of a medication for treatment effect while limiting traditional side effect profiles of oral medications.

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**Figure 1.** Picture of the Propel on the left side and the Propel Mini on the right side. The Propel Mini is smaller than the original Propel.



**Figure 2.** Picture of the Propel applicator is straight while the Propel Mini applicator has a curved tip to assist the delivery of the Propel Mini into the frontal sinus. Both applicators have a clear tip to allow easy deployment of the sinus implant into the correct sinus location.

implant into the correct location. Endoscopic visualization can be used to confirm the correct placement of the Propel Mini in the frontal sinus and circumferential contact with the sinus mucosa in the frontal sinus ostium to maximize effect of the sinus implant. The stent has been approved for placement after frontal sinusotomy. In the controlled trial, there was no specific form of frontal sinusotomy required, i.e. Draf I/II, but

only that the treatment side mirrored the placebo side [3]. The form of sinusotomy was deferred to surgeon's clinical judgment.

Postoperatively, patients are encouraged to perform copious saline sprays and irrigations in order to keep the sinonasal cavities moist and prevent crusting. The implant releases steroid locally and decreases the need for immediate postoperative steroid rinses, steroid sprays, or systemic oral steroids to maintain sinus patency. Patients should undergo routine postoperative surgical visits with sinus debridement as needed. The steroid eluting sinus implants are biodegradable and do not need to be removed. However, they can be removed at any point in the office during the postoperative setting depending on surgeon preference and treatment effect. The implant is bioabsorbable, and at the 30- and 60-day mark, only 15% and 0.2% of the stent material is present respectively [5].

In animal model study, this bioabsorbable sinus implant was able to deliver local efficacious amounts of steroid with negligible systemic absorption [6]. When comparing mucosal drug concentrations versus plasma drug concentrations, there was noted to be minimal systemic exposure to the steroid. There was also a time-dependent release of steroids noted, with peak mucosal concentrations during the 7–13-day time frame and >90% release of medication in the first 13 days.

### 3. Clinical profile

Sinus surgery in the frontal sinus has a predilection for scarring and is the most difficult to address surgically [7]. Persistent frontal sinus disease after surgery is secondary to the narrow and small frontal sinus ostium. There is a 2–11% rate of persistent symptoms attributable to frontal sinusitis or stenosis following ESS [8]. The leading causes of failure in frontal sinus surgery are edematous mucosa (92% of patients), neo-osteogenic bone in the frontal recess (46%), and scarring of the middle turbinate laterally (48%) [7]. Complete surgical dissection of the frontal recess and creating a large frontal sinus ostium is key; however, the chronic nature of mucosal inflammation and scarring after endoscopic frontal sinusotomy can influence outcomes. One of the important factors to determine frontal sinus patency is dependency on continued postoperative therapy, which includes systemic or topical steroids. Topical steroid treatments have varied penetrance in the frontal sinus recess [9] but the Propel Mini is a device that can provide continuous and steady delivery of topical steroid over a period of 30 days. Therefore, using the Propel Mini in the frontal recess and ostium provides a uniform treatment of the topical steroid and minimizes the need for systemic steroid treatment that decreases mucosal inflammation and ostium stenosis after sinus surgery.

The Propel Mini sinus is approved for patients with CRS at least 18 years of age or higher following ethmoid or frontal sinus surgery. Contraindications for the use of Propel Mini are for patients with intolerance to mometasone furoate and hypersensitivity to lactide, glycolide, or caprolactone copolymers.

A recent study has shown that the Propel Mini can be a safe and efficacious option in the management of postoperative frontal sinus disease [3]. This was a prospective randomized blinded controlled study comparing frontal sinuses that received a Propel Mini sinus implant with the contralateral frontal sinus receiving no implant in a total of 80 patients undergoing the same endoscopic frontal sinus surgery for CRS. The frontal sinuses were graded 30 days postoperatively by clinical investigators and an independent, blinded reviewer (Figure 3). In the treatment group, there was a 56% reduction in need for oral steroids, a 75% reduction in the need for surgical intervention, and a 32% greater diameter in the frontal sinus ostium relative to the control group. During the study, there were no implant-related adverse effects. There were five adverse events, which were headache, eyelid swelling, epistaxis, recurrent sinus disease, and increased sinus pressure; however, these adverse effects were not implant-related.

The results from the Propel Mini study are consistent with previous Propel sinus implant studies in the management of CRS. A 2012 efficacy meta-analysis looked at the effect of steroid-impregnated sinus implants in the management of CRS [10]. Two prospective, double-blinded, randomized trials that included 143 patients confirmed the benefit of steroid-eluting stents in ethmoid cavity healing postoperatively. Both included studies that used the Propel mometasone furoate sinus implant. In the treated ethmoid cavities, the use of the Propel stent reduced postoperative interventions by 35%, lysis of adhesions by 51%, and the need for oral steroids by 40%. In addition, there was a frank reduction in nasal polyposis by 46%.

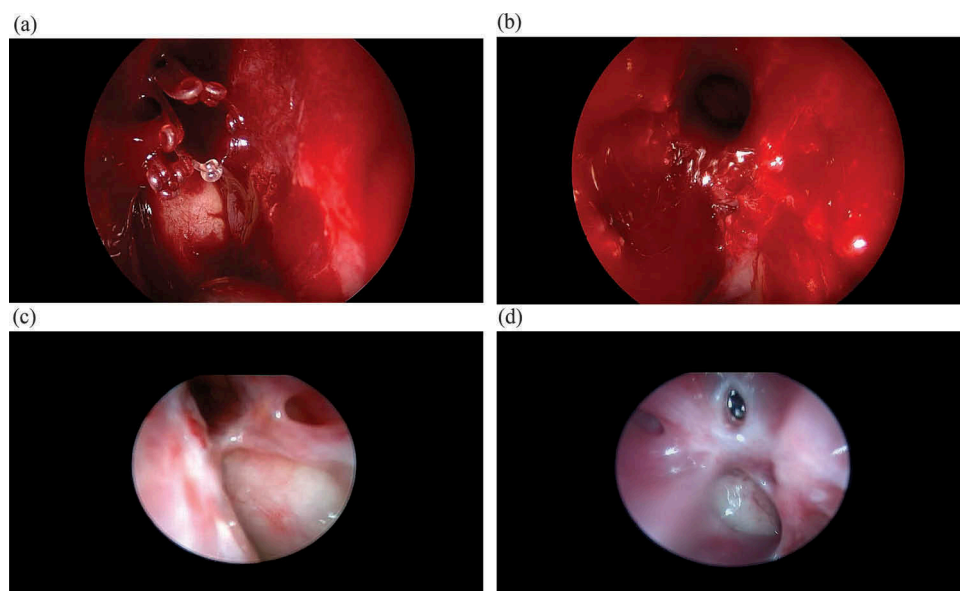
The adverse effects of Propel sinus implants are minimal. In three clinical trials studying the Propel stent, 400 sinus implants have been deployed in 205 patients with CRS [5,11]. The most common adverse events of the clinical trials were sinusitis (32%), headache (5.4%), and epistaxis (2%). No life-threatening or serious sequela have been reported.

#### 4. Alternative technologies

Currently, the Propel and the Propel Mini are the only FDA-approved sinus implants for use in the sinonasal passages postoperatively to optimize healing and minimize complications after ESS. Prior to the FDA approval of the PROPEL stents, treatment of the frontal sinuses was limited to topical intranasal therapies. Previous studies assessing topical penetration of the frontal sinus with nasal steroids have shown inconsistent results [12,13]. One study comparing the efficacy of three methods of nasal irrigation on the distribution of medications in the sinuses revealed that using a nasal douche, spray, or aerosol treatment had poor frontal sinus penetration [12]. A cadaver study assessing irrigation penetration of the sinuses showed the frontal sinus had the most variable concentration of medications and was dependent on heavy irrigating systems [13]. Therefore, the Propel Mini sinus implant is able to optimize topical and local steroid delivery to the frontal sinus mucosa that would otherwise have little to no penetrance by nasal irrigation.

Attempts at treatment of the frontal sinus with off-label devices have not had lasting success. The first documented case of surgically placed frontal sinus devices was in 1905 where Ingals used gold tubes as sinus stents [14]. In 2003, the first dexamethasone-coated polymer was endoscopically placed into the frontal sinus after endoscopic frontal sinusotomy in a human [15]. The dexamethasone-coated polymer matrix delivered medication for 2 weeks prior to removal in three patients who underwent Draf II/III frontal sinus ostia enlargement. The first trial was successful in management of the frontal sinus postoperatively but was a primitive approach and dependent on an extensive process to impregnate the polymer with steroids. The polymer also was not bioabsorbable and required removal.

Acclarent (Menlo Park, CA) developed the Relieva Stratus MicroFlow Spacer, a stent that was approved by FDA for sinus treatment in 2009. The Relieva Stratus Microflow Spacer was a



**Figure 3.** (a) Endoscopic picture of the right frontal sinus ostium after placement of PROPEL mini. (b) Endoscopic picture of left frontal sinus ostium without Propel Mini. (c) Endoscopic picture of the right frontal sinus ostium at day 30. (d) Endoscopic picture of the left frontal sinus ostium at day 30 demonstrating frontal sinus narrowing.



minimally invasive stent placed endoscopically and designed for the ethmoid sinuses and eventually modified for the frontal sinuses. The device was a temporary implant with a micropore reservoir system only approved for release of saline. After 28 days, the implant had to be removed, typically in the office. The Microflow Spacer was used off-label with triamcinolone acetonide within the micropore delivery system in a 2011 study including 23 patients [16]. Results were promising within the ethmoid cavities with significant reduction in postoperative SNOT-20 and Lund MacKay scores. However, the Microflow Spacer was eventually removed from the market because of inappropriate claims [17]. The Microflow Spacer was being marketed as a steroid-release reservoir system despite FDA approval only for use with saline. The Microflow Spacer is no longer marketed or available.

## 5. Expert opinion

Topical delivery of medications to the paranasal sinus with biocompatible implants is the future in management of CRS. The Propel Mini sinus implant is the first of its kind to be shown as an efficacious option in managing the most surgically challenging sinus. Propel and Propel Mini are coated with steroids, but previous animal model studies have evaluated polymers impregnated with paclitaxel [18] to reduce postoperative scarring and with doxycycline-releasing stents to decrease bacterial colonization [19]. Therefore, there will likely be a trend toward developing biologically active medications other than steroids, to be released locally in the sinonasal mucosa with implants. One potential type of medication that has a large potential is antibiotic-coated implants.

Currently, there is a trend toward employing anti-cytokine-based biologic therapies in asthma. Medications dedicated to inhibiting IL-4, IL-5, IL-13, and anti-IgE have been promising in controlling asthma inflammation. Specifically, omalizumab (Xolair) is a humanized monoclonal immunoglobulin E-targeted antibody that is an FDA-approved therapy for inadequately controlled asthma [20]. There is immunological crosstalk between the processes of asthma and CRS. Cytokine and inflammatory cascades are shared between the adaptive immune response of both processes. It is possible that these biologic therapies can be applied to implantable devices for use in the sinonasal cavities to manage CRS. Therefore, it is possible that locally applied biologic immunotherapies can better control local inflammatory responses in CRS similar to the steroids in PROPEL stents. That is an area of future research.

Finally, in an effort to minimize the extent of trauma during sinus surgery performed in CRS patients, balloon catheter dilation is being applied more commonly as an adjunct in the office and operating room. The goal of dilation is to open and preserve the natural functional outflow tracts of the sinuses. However, the effects of dilation can be transient with obstruction returning either secondary to anatomy or inflammation. Therefore, there may be a role for placement of PROPEL stents after balloon

dilation in order to maintain ostium patency and reduce inflammation.

Developing technologies that reduce postoperative inflammation and scarring is key to ESS success. Therefore, there is an increasing role for adjuncts in postoperative management that preserve ostium patency. Topical intranasal steroid or other medication rinses historically have been used but penetrance is variable and is user dependent. Implantable devices with slow-release capability to release steroid or other medications have and can be used to maximize treatment effects of a surgical intervention. However, the ability to deliver medications via a bioabsorbable material in a sustained-release form is a difficult endeavor. Developing new therapies for local release of medications that have shown clinical benefits is a difficult and arduous process. As such, the Propel and Propel Mini with their steroid coating are the first and only FDA-approved implantable option for CRS patients who have undergone ESS.

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## Declaration of interest

J Han is a consultant for Intersect. The authors have no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed.

## References

Papers of special note have been highlighted as either of interest (\*) or of considerable interest (\*\*) to readers.

1. Propel Sinus Stent. Instructions for usage, Intersect ENT; 2016. Intersect ENT. Available from: <http://propelopens.com/the-propel-advantage/clinical-data>
2. Intersect ENT. Intersect ENT announces FDA approval of new steroid-releasing implant, allowing more chronic sinusitis patients to benefit from localized drug delivery; 2012. Available from: [http://propelopens.com/wp-content/uploads/2014/04/IntersectENT\\_PressRelease-PROPEL\\_mini\\_FDA\\_Approval\\_2012\\_11\\_06.pdf](http://propelopens.com/wp-content/uploads/2014/04/IntersectENT_PressRelease-PROPEL_mini_FDA_Approval_2012_11_06.pdf)
3. Smith TL, Singh A, Luong A, et al. Randomized controlled trial of a bioabsorbable steroid-releasing implant in the frontal sinus opening. *Laryngoscope*. 2016 Jul 1. epublied. DOI:10.1002/lary.26140
- **Landmark article demonstrating the efficacy of the Propel Mini implant for usage in the frontal sinuses.**
4. Onrust SV, Lamb HM. Mometasone furoate. A review of its intranasal use in allergic rhinitis. *Drugs*. 1998;56:725–745. DOI:10.2165/00003495-199856040-00018
5. Marple BF, Smith TL, Han JK, et al. ADVANCE II: a prospective, randomized study assessing safety and efficacy of bioabsorbable steroid-releasing sinus implants. *Otolaryngol HNS*. 2012;146:1004–1011.
- **Clinical trial documenting the effects of PROPEL in managing CRS.**
6. Li PM, Downie D, Hwang PH. Controlled steroid delivery via bioabsorbable stent: safety and performance in a rabbit model. *Am J Rhinol Allergy*. 2009;23:591–596. DOI:10.2500/ajra.2009.23.3391
7. Valdes CJ, Bogado M, Samaha M. Causes of failure in endoscopic frontal sinus surgery in chronic rhinosinusitis patients. *Int Forum Allergy Rhinol*. 2014;4:502–506. DOI:10.1002/alr.21307
8. Hosemann W, Kuhnel T, Held P, et al. Endonasal frontal sinusotomy in surgical management of chronic sinusitis: a critical

- evaluation. *Am J Rhinol.* **1997**;11:1–9. DOI:[10.2500/105065897781446793](https://doi.org/10.2500/105065897781446793)
9. Aggarwal R, Cardozo A, Homer JJ. The assessment of topical nasal drug distribution. *Clin Otolaryngol Allied Sci.* **2004**;29:201–205. DOI:[10.1111/j.1365-2273.2004.00797.x](https://doi.org/10.1111/j.1365-2273.2004.00797.x)
  10. Han JK, Marple BF, Smith TL, et al. Effect of steroid-releasing sinus implants on postoperative medical and surgical interventions: an efficacy meta-analysis. *Int Forum Allergy Rhinol.* **2012**;2:271–279. DOI:[10.1002/alr.21044](https://doi.org/10.1002/alr.21044)
  - **Original clinical work documenting the efficacy of a steroid impregnated implant in managing CRS.**
  11. Murr AH, Smith TL, Hwang PH, et al. Safety and efficacy of a Novel Bioabsorbable, steroid-eluting sinus stent. *Int Forum Allergy Rhinol.* **2011**;1:23–32. DOI:[10.1002/alr.20020](https://doi.org/10.1002/alr.20020)
  12. Wormald PJ, Cain T, Oates L, et al. A comparative study of three methods of nasal irrigation. *Laryngoscope.* **2004**;114:2224–2227. DOI:[10.1097/01.mlg.0000149463.95950.c5](https://doi.org/10.1097/01.mlg.0000149463.95950.c5)
  13. Abadie W, McMains K, Weitzel E. Irrigation penetration of nasal delivery systems: a cadaver study. *Int For All Rhin.* **2011** Jan–Feb. DOI:[10.1002/alr.20002](https://doi.org/10.1002/alr.20002)
  14. Ingals EE. New operations and instruments for draining the frontal sinus. *Tr Am Laryng Rhin Otol Soc.* **1905**;11:183–189.
  15. Hosemann W, Schindler E, Wiegrebe E, et al. Innovative frontal sinus stent acting as a local drug-releasing system. *Eur Arch Otorhinolaryngol.* **2003** Mar;260(3):131–134.
  16. Catalano P, Thong M, Weiss R, et al. The microflow spacer: a drug-eluting stent for the ethmoid sinus. *Indian J Otolaryngol Head Neck Surg.* **2011** Jul–Sep;63(3):279–284. DOI:[10.1007/s12070-011-0258-y](https://doi.org/10.1007/s12070-011-0258-y)
  17. U.S. Attorney's Office, Department of Justice, Former Acclarent, Inc. Executives charged with securities fraud and crimes related to sale and distribution of medical devices; **2015** Apr. Available from: <https://www.justice.gov/usao-ma/pr/former-acclarent-inc-executives-charged-securities-fraud-and-crimes-related-sale-and-0>
  18. Hermann BW, Citardi MJ, Volger G, et al. A preliminary report on the effects of paclitaxel-impregnated stents on nasal sheep mucosa. *Am J Rhinol.* **2004**;18:119–124.
  19. Huvenne W, Zhang N, Tijsma E, et al. Pilot study using doxycycline releasing stents to ameliorate post-operative healing quality after sinus surgery. *Wound Repair Regen.* **2008**;16:757–767. DOI:[10.1111/j.1524-475X.2008.00429.x](https://doi.org/10.1111/j.1524-475X.2008.00429.x)
  20. Pelaia G, Vatrella A, Maselli R. The potential of biologics for the treatment of asthma. *Nature Reviews Drug Discovery.* **2012** Dec;11:958–972. DOI:[10.1038/nrd3792](https://doi.org/10.1038/nrd3792)