RESEARCH METRICS FOR GDUFA II MANDATED OUTCOME REPORTING

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External Research Studies

Since FY 2013, OGD has awarded 36 research contracts and 69 grants:

Fiscal Year	Number of External Research Projects Awarded using GDUFA Funds	
	New Projects	Ongoing Projects
2017	7	39
2016	16	38
2015	22	41
2014	35	16
2013	29	--

- All projects listed as "Ongoing" received GDUFA funding for more than 1 year. There are other projects not included in this table in which work was continued for more than 1 year but were on no-cost extensions.
- The FDA website (www.fda.gov/GDUFAregscience) lists all the GDUFA funded grants and contracts awarded by OGD

Focus on Complex Products

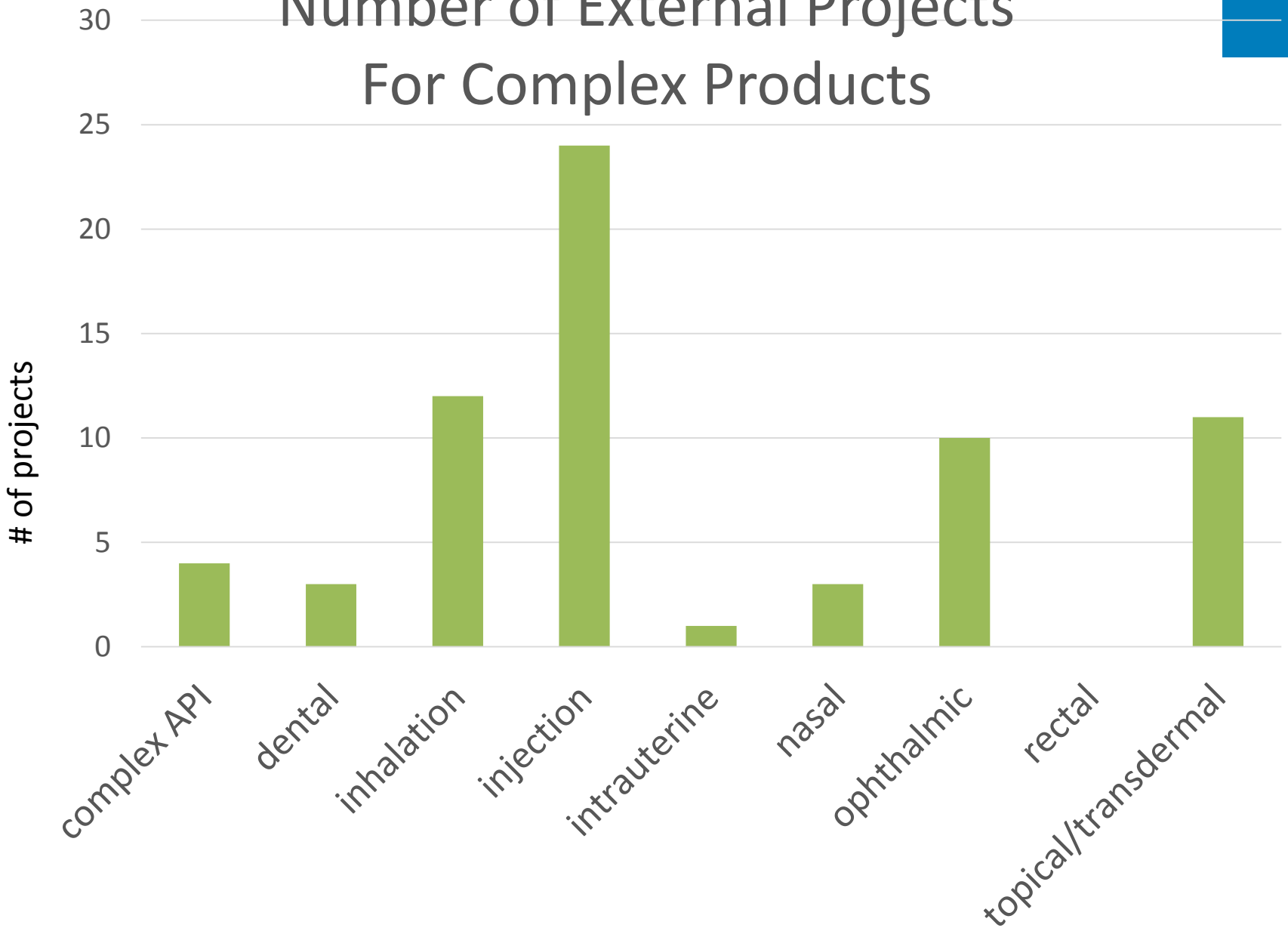
Since FY 2013, the research focus has turned to complex products

Fiscal Year	Number of External Research Projects Awarded using GDUFA Funds	
	Total Projects	Complex Products
2017	46	30 (65%)
2016	54	35 (64%)
2015	63	37 (58%)
2014	51	30 (58%)
2013	29	17 (58%)

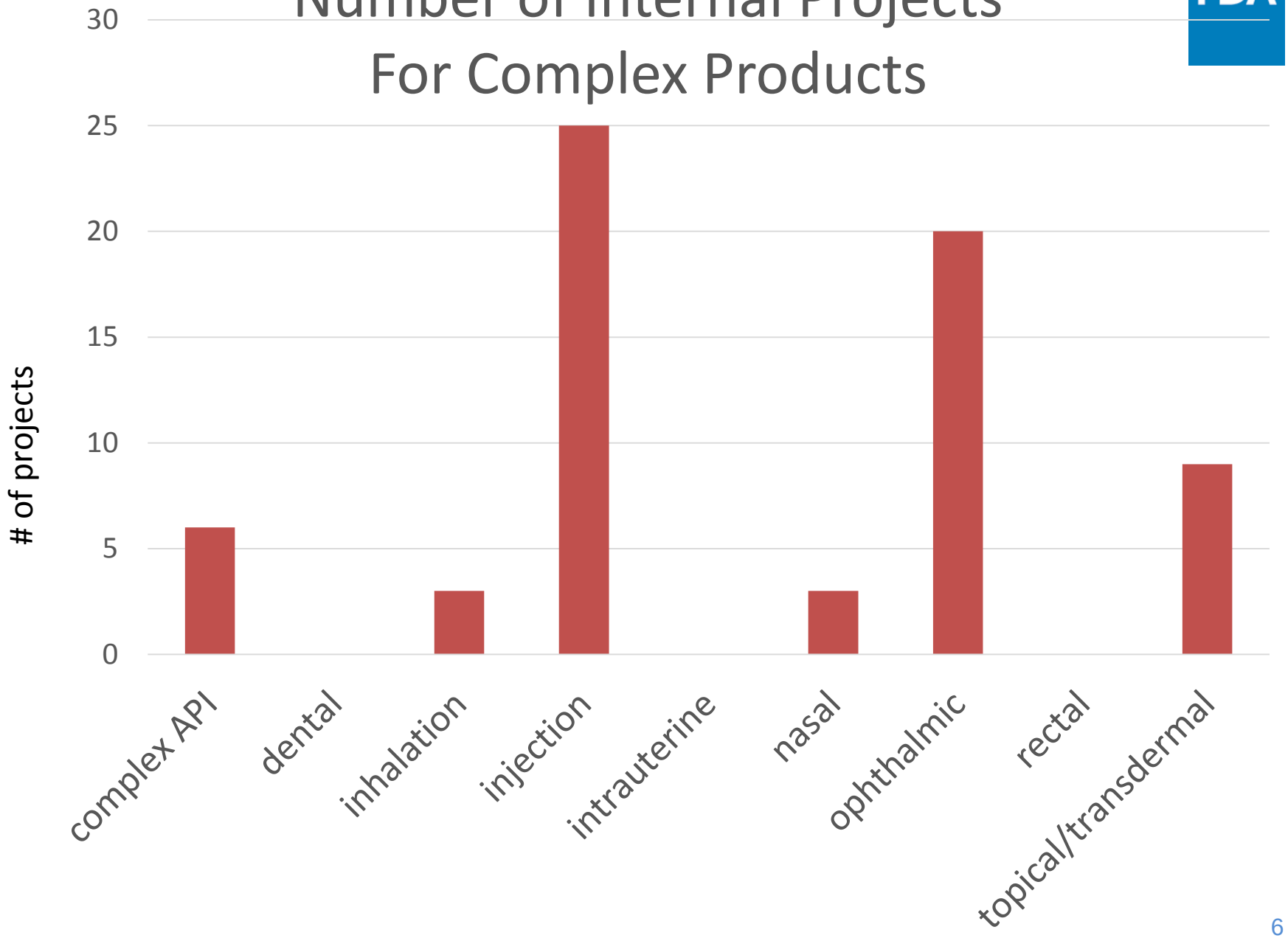
Internal Research Studies

- More than 80 completed research projects and 40 ongoing projects with FDA labs and offices since FY13:
  - Center for Devices and Radiological Health
  - National Center for Toxicological Research
  - Office of Regulatory Affairs
  - Center for Drug Evaluation and Research
    - Office of Pharmaceutical Quality
    - Office of Surveillance and Epidemiology
    - Office of Translational Sciences

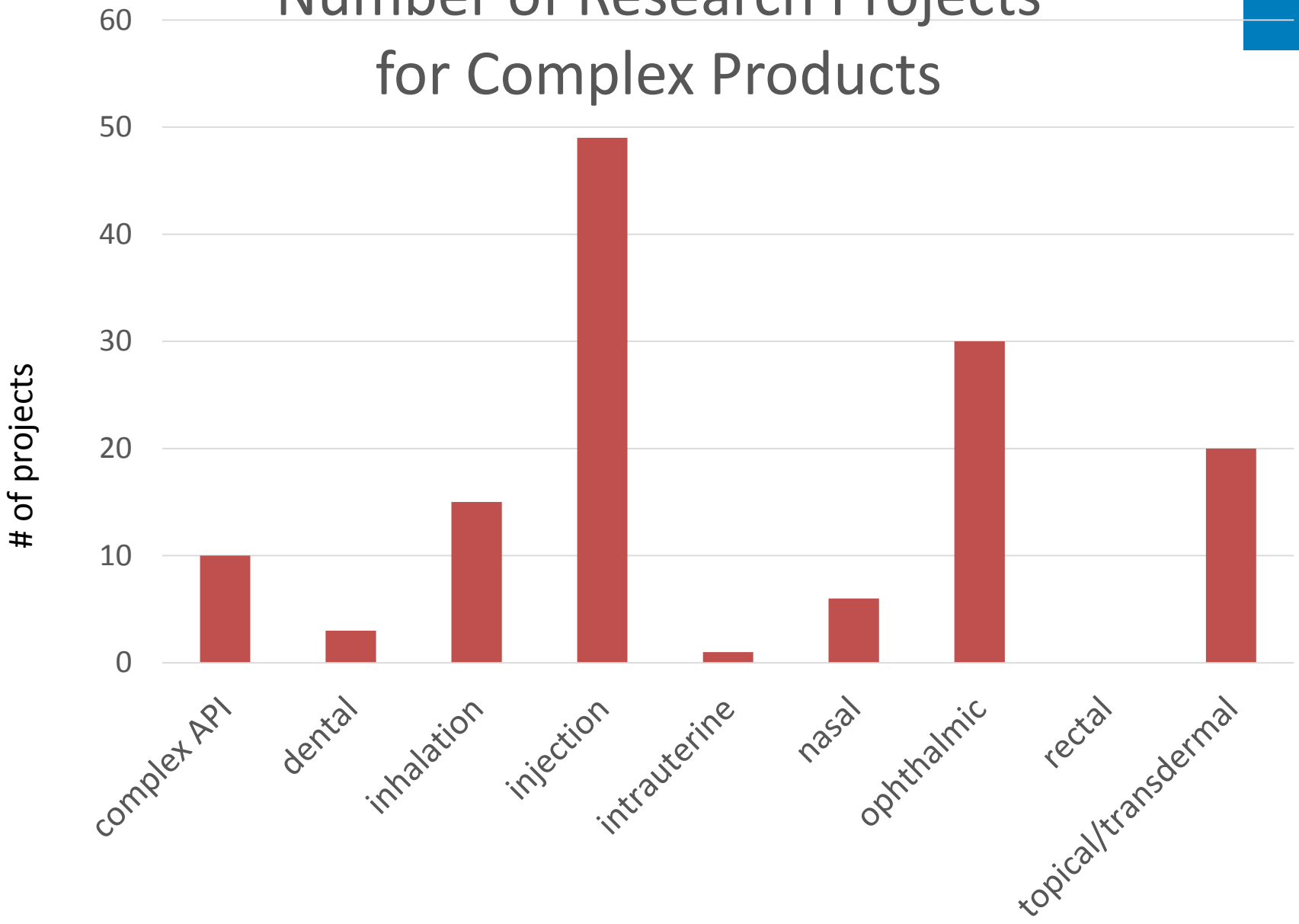
Number of External Projects For Complex Products



Number of Internal Projects For Complex Products



Number of Research Projects for Complex Products



GDUFA II Commitment Letter

https://www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM525234.pdf

H. Regulatory Science Enhancements

Annually, FDA will report on its website the extent to which GDUFA regulatory science-funded projects support:

- the development of generic drug products

Pre-ANDA meetings Controlled Correspondences

Product Specific Guidances

- the generation of evidence needed to support efficient review and timely approval of ANDAs

ANDA submissions ANDA approvals

- the evaluation of generic drug equivalence.

Post-market studies Scientific communication

Research Outcomes

- Scientific communication
  - Posters
  - Presentations
  - Publications
  - Workshops
- Guidances
  - Product-specific guidances (PSGs)
  - General recommendations
- ANDAs
  - Approved ANDAs
  - Pre-ANDA meetings
- Other regulatory submissions
  - Controlled Correspondences
  - Citizen Petitions
- Databases/Tools/Models
  - UCSF Excipients Browser (http://excipients.ucsf.bkslab.org/)
  - Codes that are publicly available

Research outcomes will be linked to each GDUFA research project

External Scientific Communication

Communication Type	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Journal Articles	11	15	45	61	29
Presentations	20	21	43	78	39
Posters	10	19	68	105	42

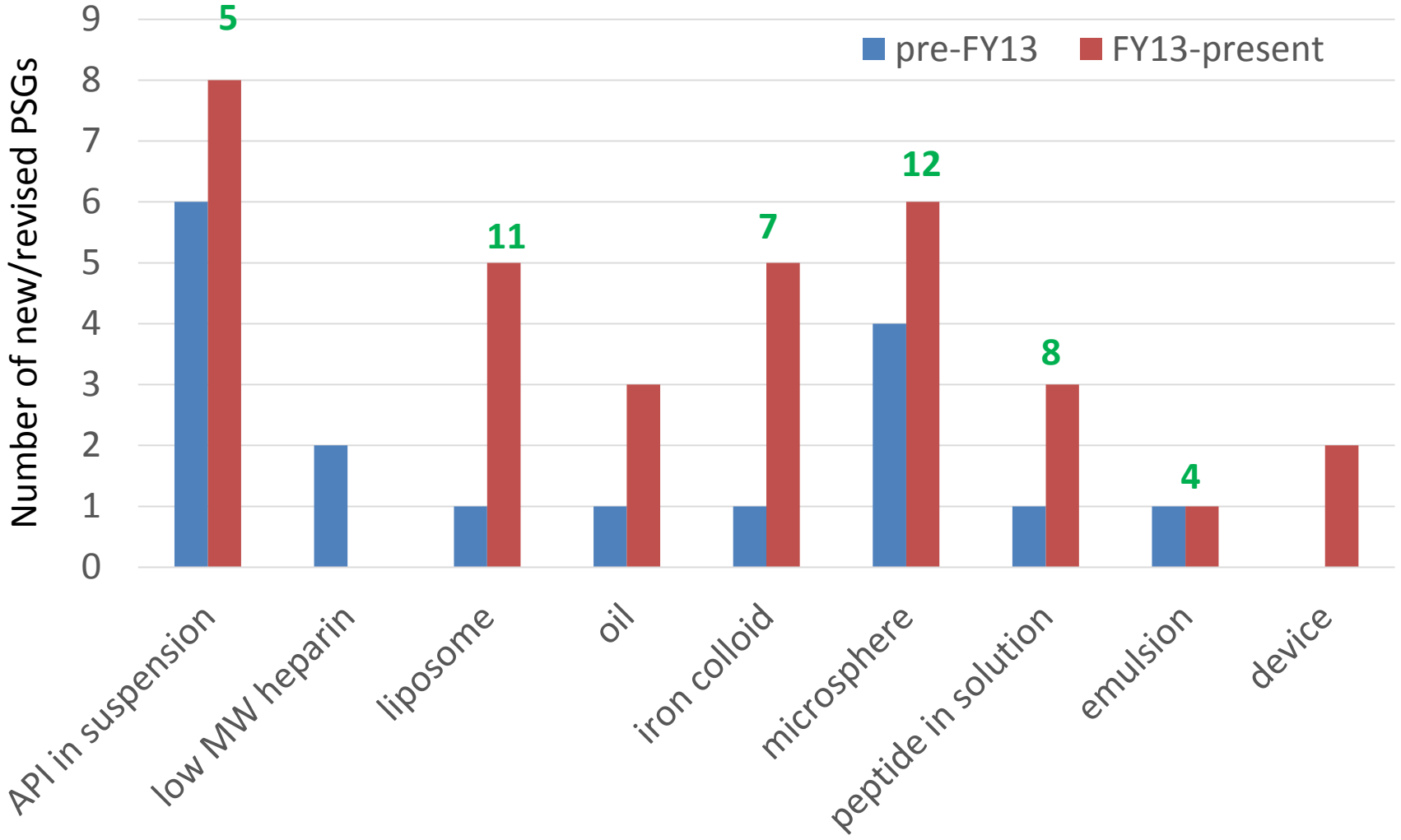
Public Workshops

- New Insights for Product Development and Bioequivalence Assessments of Generic Orally Inhaled and Nasal Drug Products (January 9, 2018)
- Overcoming Barriers to the Development of, and Improving Patient Access to, Topical Dermatological Generic Drug Products (October 20, 2017)
- Demonstrating Equivalence of Generic Complex Drug Substances and Formulations: Advances in Characterization and In Vitro Testing (October 6, 2017)
- Leveraging Quantitative Methods and Modeling to Modernize Generic Drug Development and Review (October 2 - 3, 2017)
- Oral Absorption Modeling and Simulation for Formulation Development and Bioequivalence Evaluation Workshop (May 19, 2016)

Impact of GDUFA Research on Guidance Development and pre-ANDA Communications

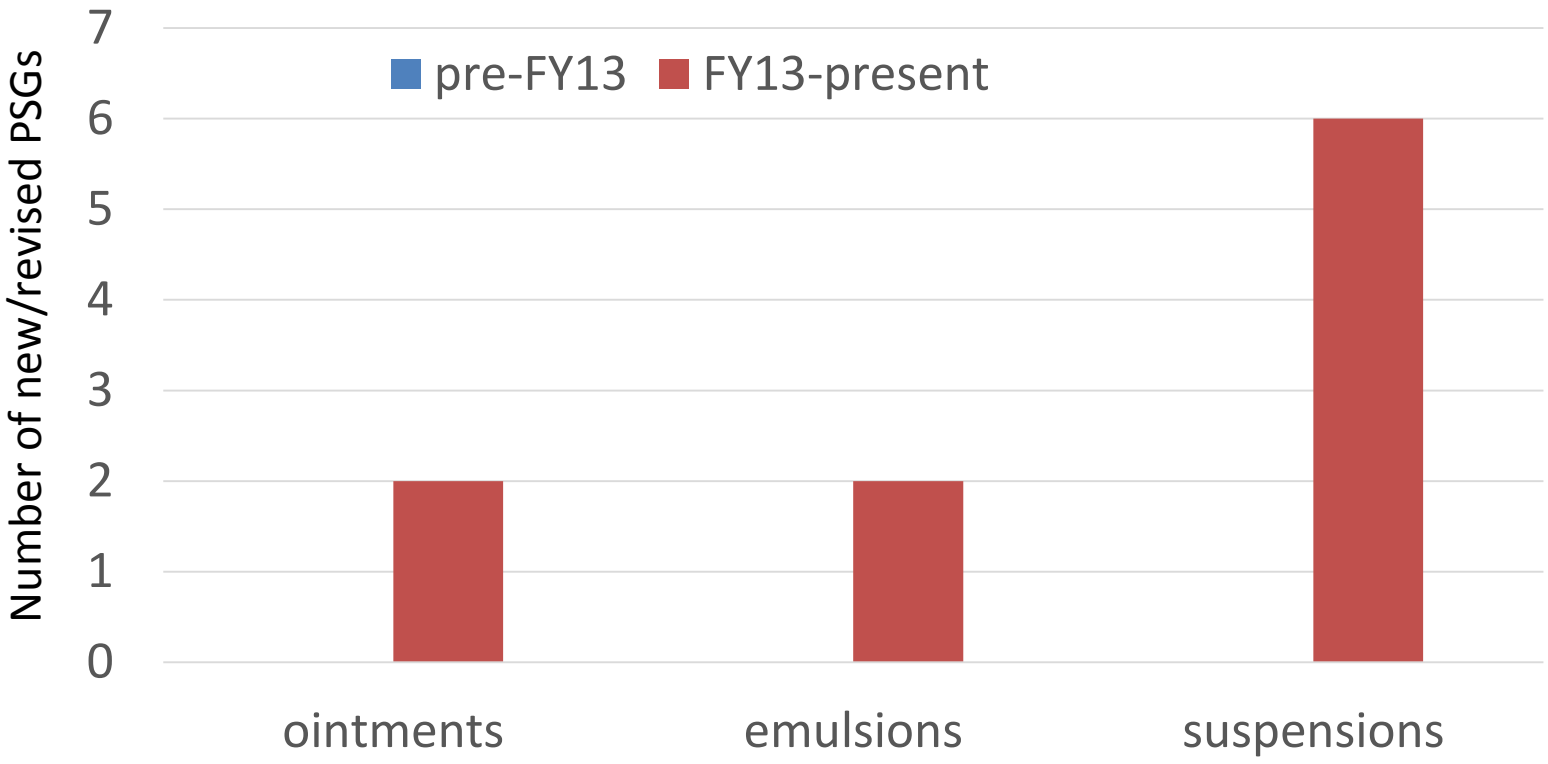
- Scientific research informs PSG development:
  - Development/evaluation of novel analytical techniques, methods, assays
  - Characterization of the reference listed drug
  - Alternative approaches to demonstrate bioequivalence
- More PSGs developed across a spectrum of therapeutic categories
- Research conducted for many complex drug products to inform communications with Industry during the pre-ANDA stage

PSGs
Complex Injectable Drug Products



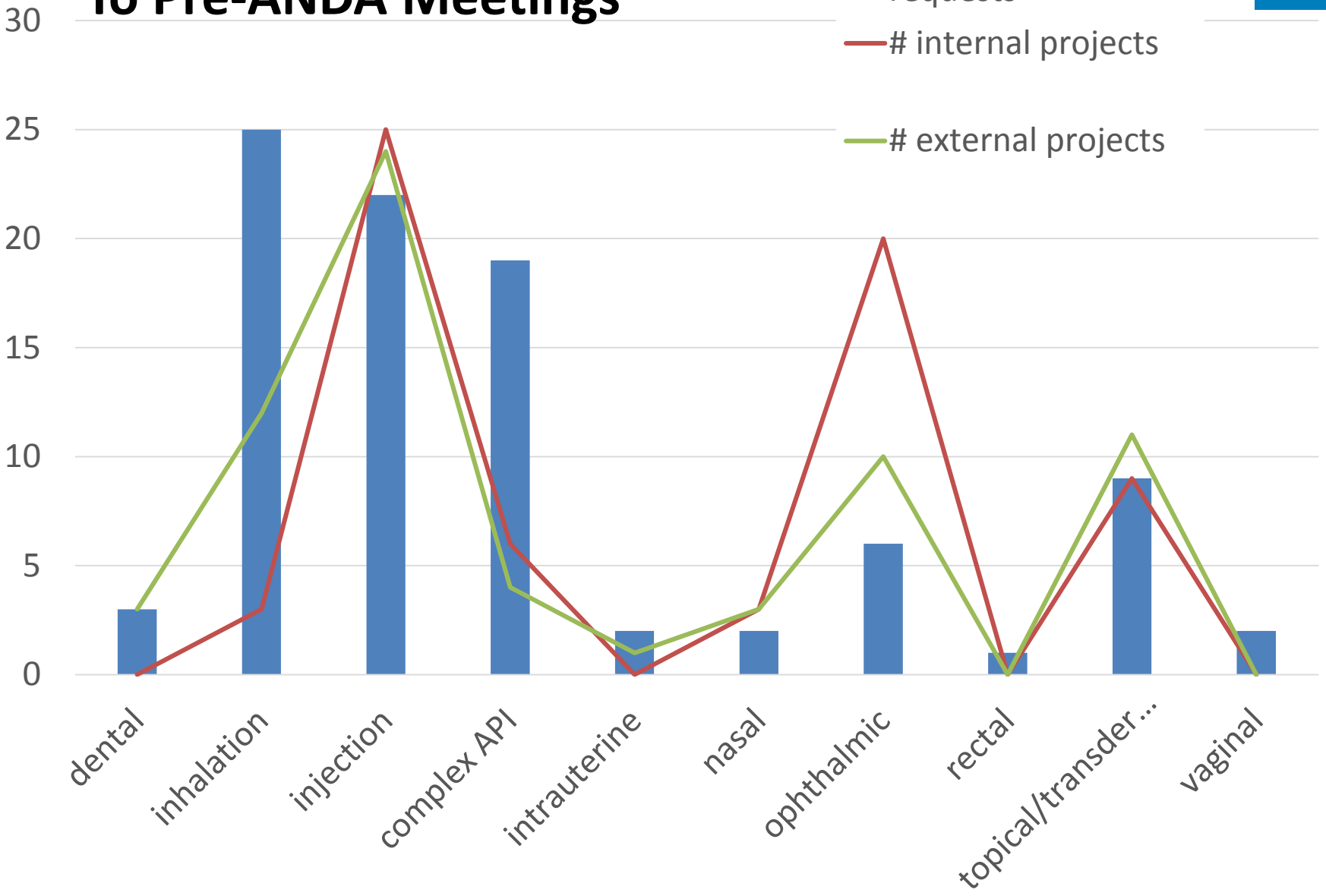
GDUFA research (#s in green) contributed to the development of new and revised PSGs for many complex injectable drug products

PSGs
Ophthalmic Drug Products



GDUFA research (10 external projects; 19 internal projects) contributed to the recommendation of the in vitro option for ophthalmic products

FY13-FY17 Linkage of Research To Pre-ANDA Meetings



Notable First-Generic ANDA Approvals

- Glatiramer acetate injection (Copaxone), 40 mg/ml (10/3/17) and 20 mg/ml (4/16/15)
  - Internal studies on characterization of glatiramer
- Mesalamine DR Tablets (Lialda), 1.2 g (6/5/17)
  - Internal and external studies on local PK
- Mometasone furoate nasal suspension (Nasonex), 50 mcg (3/22/16)
  - Internal studies on Morphologically-Directed Raman Spectroscopy (MDRS)

GDUFA Regulatory Science Webpage

- www.fda.gov/GDUFARegScience
  - Research priorities
  - Guidances and reports
  - Research publications
  - Collaboration opportunities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