**IMMUNO-ONCOLOGY MOVES FAST**

945 immuno-oncology studies over the last 10 years

- 305: 2016
- 127: 2015
- 52: 2014
- 28: 2013
- 13: 2012
- 9: 2011
- 7: 2010

- 14: 2009

Rapid approvals

- Pembrolizumab: Metastatic melanoma only 3 years after Phase II studies began

- Pembrolizumab: Metastatic PD-L1+ NSCLC with a companion diagnostic test, followed just 1 year later

Q1-Q3 2016 7 oncology breakthrough therapy designations

- 4 = Kinase Inhibitor
- 1 = Bcl-2 Inhibitor
- 2 = Immuno-therapies

**IMMUNO-ONCOLOGY CLINICAL TRIALS**

Immuno-therapies need novel endpoints

- Durable responses
- Atypical responses
- Composite endpoints

**IMMUNO-ONCOLOGY ADVERSE EVENTS**

Immune-related AEs must be managed appropriately by trained investigators via monitoring programs

- Colitis/diarrhea
- Hepatitis
- Iridocyclitis
- Hypophysitis
- Pancreatitis
- Nephritis
- Neuropathy
- Lymphadenopathy
- Pruritus
- Rash