PARTNERING ON CLINICAL TRIALS

NEW INVESTIGATOR CLINICAL TRIAL COURSE – CCTG
AUGUST 2019

DANIEL MARTINEZ
MEDICAL DIRECTOR ONCOLOGY – AMGEN CANADA

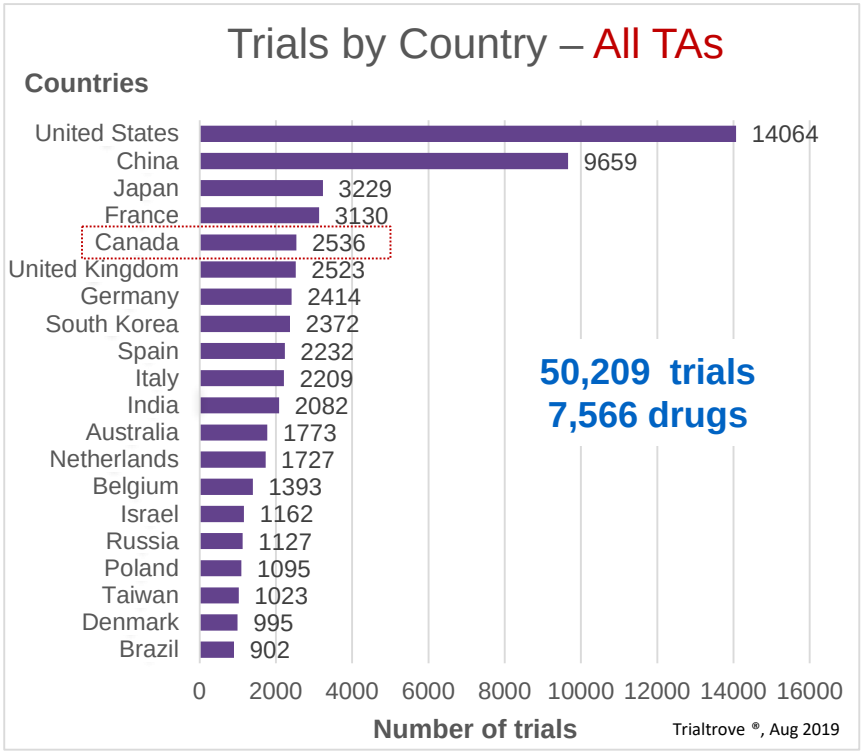
AMGEN®

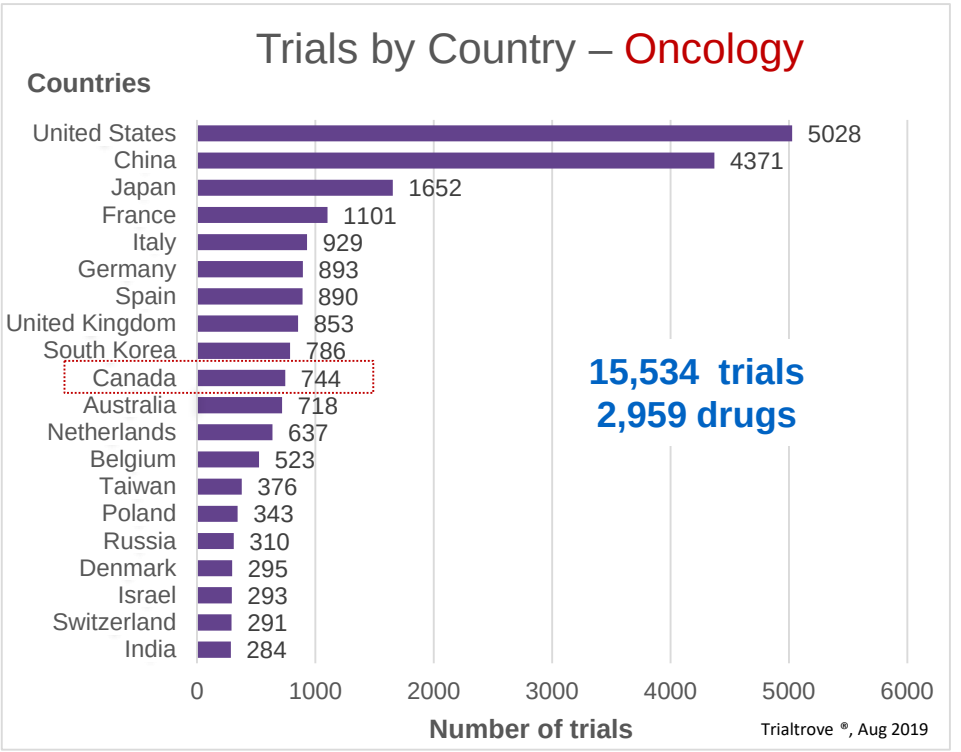
DISCLOSURE

I have the following relevant financial relationship to disclose:

Employed by Amgen

TOTAL NUMBER OF TRIALS PLANNED OR OPENED





TA: Therapeutic Area
Source: https://citeline.informa.com/trials/results - last accessed: 2019-08-01

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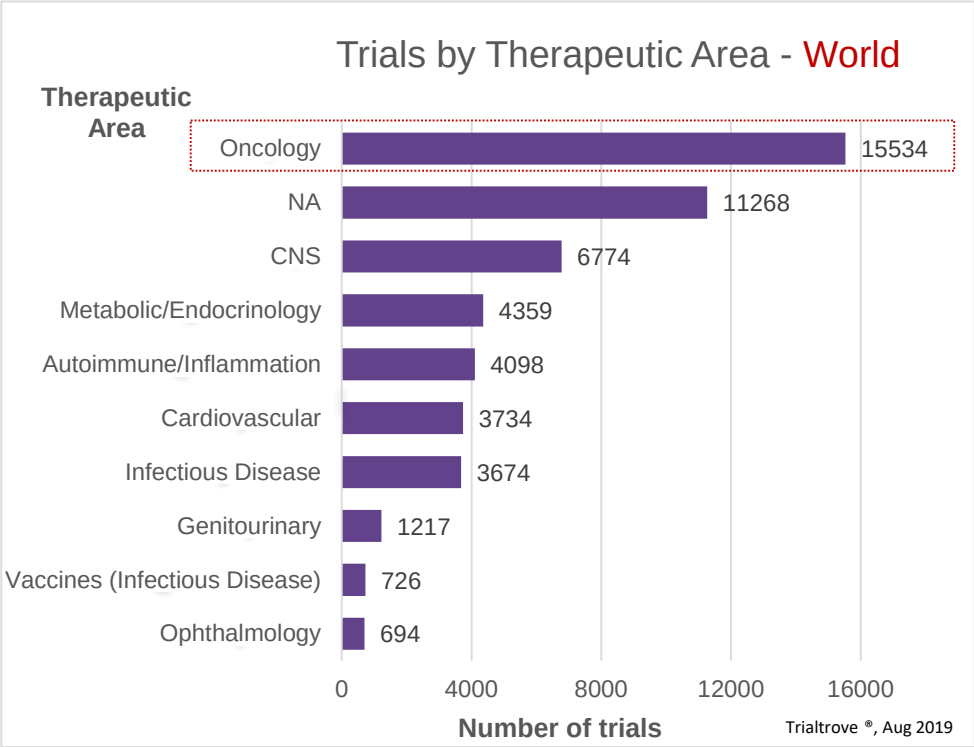
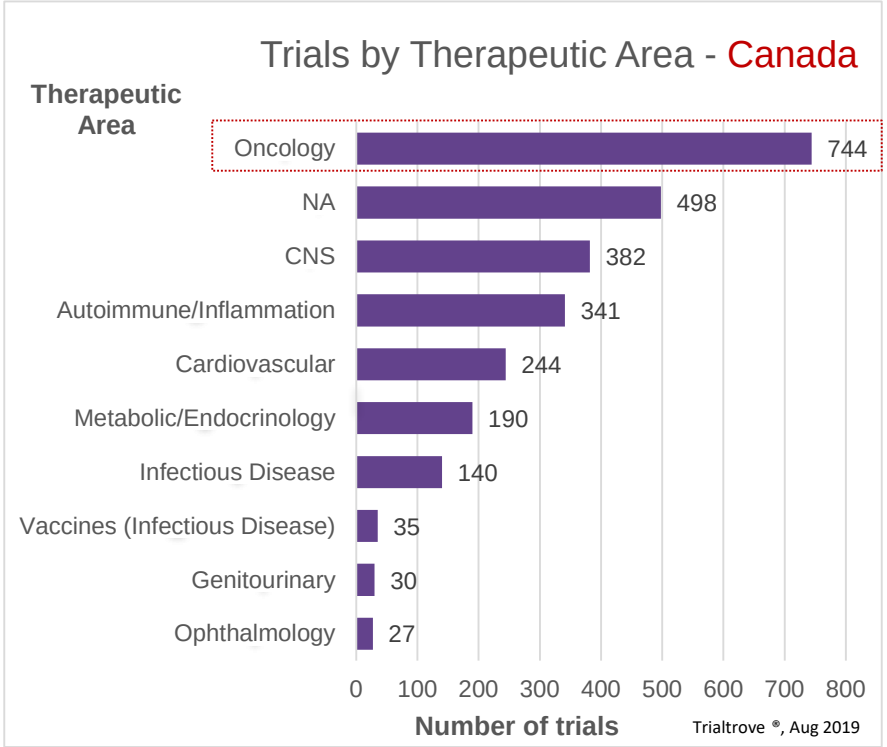
TOTAL NUMBER OF TRIALS PLANNED OR OPENED BY TA





TA: Therapeutic Area
Source: https://citeline.informa.com/trials/results - last accessed: 2019-08-01

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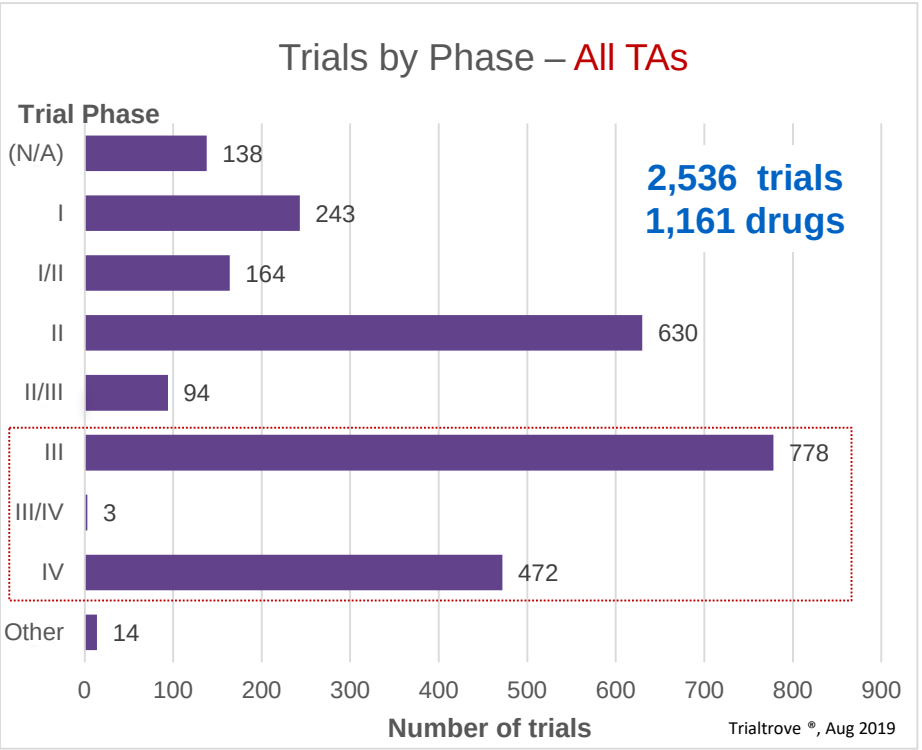
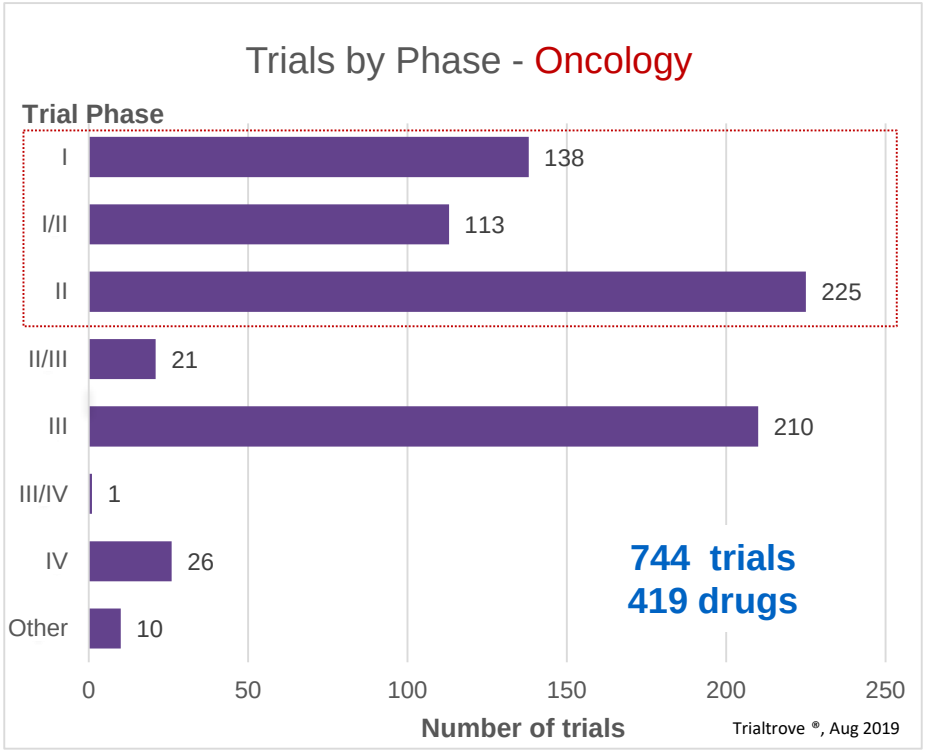
TOTAL NUMBER OF TRIALS PLANNED OR OPENED IN CANADA





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AMGEN PIPELINE

A MAJORITY
of preclinical and clinical non-oncology programs supported by
POPULATION GENETICS

The industry's largest toolkit with **13 MODALITIES***

A mix of
INNOVATIVE MOLECULES, NEW INDICATIONS, AND BIOSIMILARS

A robust and differentiated pipeline, leveraging state-of-the-art science to create medicines for serious illness. Amgen is focused on high-quality candidates that demonstrate large, clinically-relevant effects. Human genetic validation is used whenever possible to enhance the likelihood of success.

PHASE ONE

AMG 119	AMG 160	AMG 176	AMG 562	AMG 570	AMG 592
AMG 212	AMG 330	AMG 397	AMG 594	AMG 596	AMG 598
AMG 404	AMG 420	AMG 424	AMG 673	AMG 701	AMG 757
AMG 427	AMG 430	AMG 510	AMG 890	AMG 966	IMLYGIC® (talimogene laherparepvec)

PHASE TWO

AMG 714 / PRV-015	BLINCYTO® (blinatumomab)	Tezepelumab

PHASE THREE

ENBREL® (etanercept)	IMLYGIC® (talimogene laherparepvec)	KYPROLIS® (carfilzomib)
Omecamtiv mecarbil	Tezepelumab	

https://www.amgenpipeline.com/pipeline - last accessed: 2019-08-01

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THERAPEUTIC AREA Hematology/Oncology +

PHASE ONE

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AMG 212	AMG 330	AMG 397	AMG 594	AMG 596	AMG 598
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Omecamtiv mecarbil	Tezepelumab	

- Multiple Myeloma
- Colorectal Cancer
- Lung cancer
- Prostate Cancer
- Gastric Cancer
- Acute Leukemias
- CNS Cancer

https://www.amgenpipeline.com/pipeline - last accessed: 2019-08-01

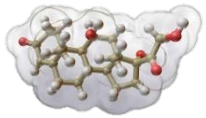
Our Oncology Strategy

Debulk, Inflame, Enhance

PRECISION ONCOLOGY

IMMUNO-ONCOLOGY

DEBULK



Targeted Therapy
Small Molecule,
Antibody
(Mcl-1, K-ras G12C)

INFLAME

BiTE®, CAR T,
Oncolytic Virus

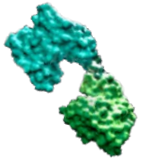
ENHANCE

BiTE®, CAR T,
Oncolytic Virus
Checkpoint Inhibitor

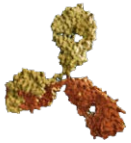
Pursuing differentiated cancer therapies with large effect sizes

We are exploring a large drug discovery toolkit

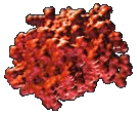
our bispecific platform represents >50% of early dev oncology



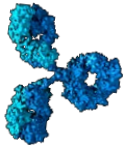
BiTE® Antibody Constructs



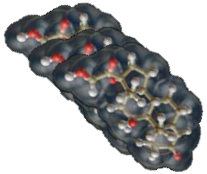
Bispecific Antibodies



Therapeutic Proteins



Monoclonal Antibodies



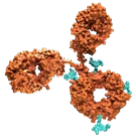
Small Molecules

siRNA

Peptides

Fusion Proteins

Oncolytic Immunotherapy Viruses



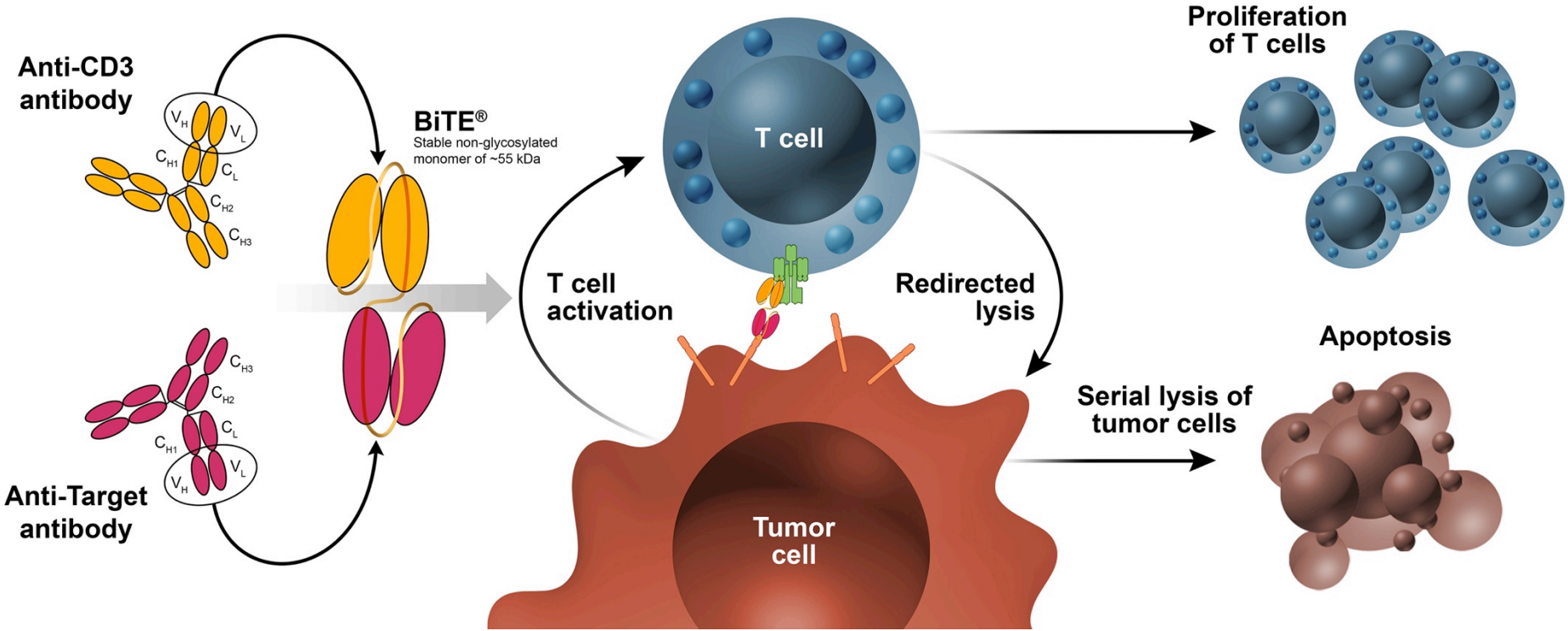
Antibody Drug Conjugates

CAR T Cells

Peptibodies

https://www.amgenoncology.com/modalities.html

How BiTE® Antibody Constructs Are Designed to Work



CD, cluster of differentiation; C_H, heavy-chain constant domain; C_L, light-chain constant domain; BiTE®, bispecific T cell engager; V_H, heavy-chain variable domain; V_L, light-chain variable domain.

1. Baeuerle PA, et al. *Cancer Res.* 2009;69:4941-4944. 2. Baeuerle PA, et al. *Curr Opin Mol Ther.* 2009;11:22-30. 3. Nagorsen D, et al. *Exp Cell Res.* 2011;317:1255-1260.

3 Key Areas of Research Innovation

Innovative clinical trial design

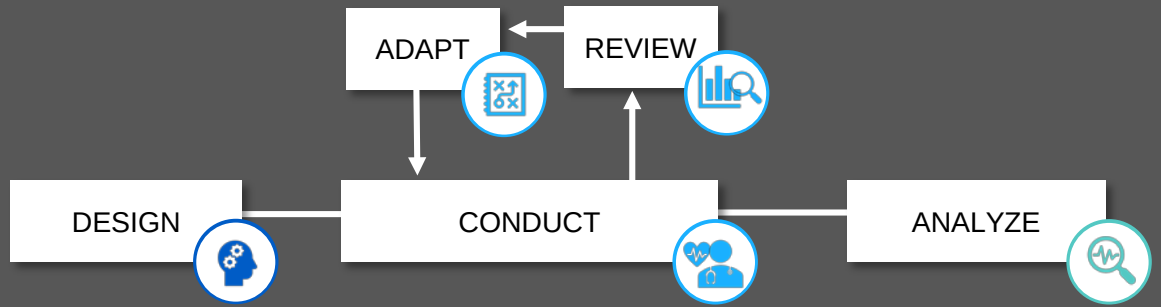
Emerging surrogate endpoints

Real-world evidence

TRADITIONAL VS. ADAPTIVE DESIGNS

TRADITIONAL DESIGN

ADAPTIVE DESIGN



INNOVATIVE CLINICAL DESIGN

Adaptive designs use accumulating information and allow modification of key trial parameters in the ongoing study as established by pre-specified rules

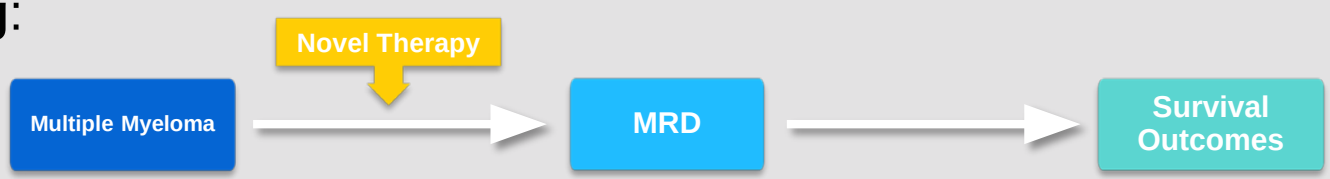
Pallmann, et al. BMC Medicine. 2018;16:29.

SURROGATE ENDPOINTS: MRD AS AN EMERGING EXAMPLE

Surrogate endpoints can reasonably likely **predict clinical benefit**

Established:

Emerging:



- Institute of Medicine 2010. Evaluation of Biomarkers and Surrogate Endpoints in Chronic Disease. Washington, DC: The National Academies Press. DOI: https://doi.org/10.17226/12869
- https://doi.org/10.17226/12869.US Department of Health and Human Services. Hematologic Malignancies: Regulatory Considerations for Use of Minimal Residual Disease in Development of Drug and Biological Products for Treatment. Draft Guidance for Industry. Oct. 2018.
- Gormley NJ, et al. *JAMA. Oncol*. 2016.

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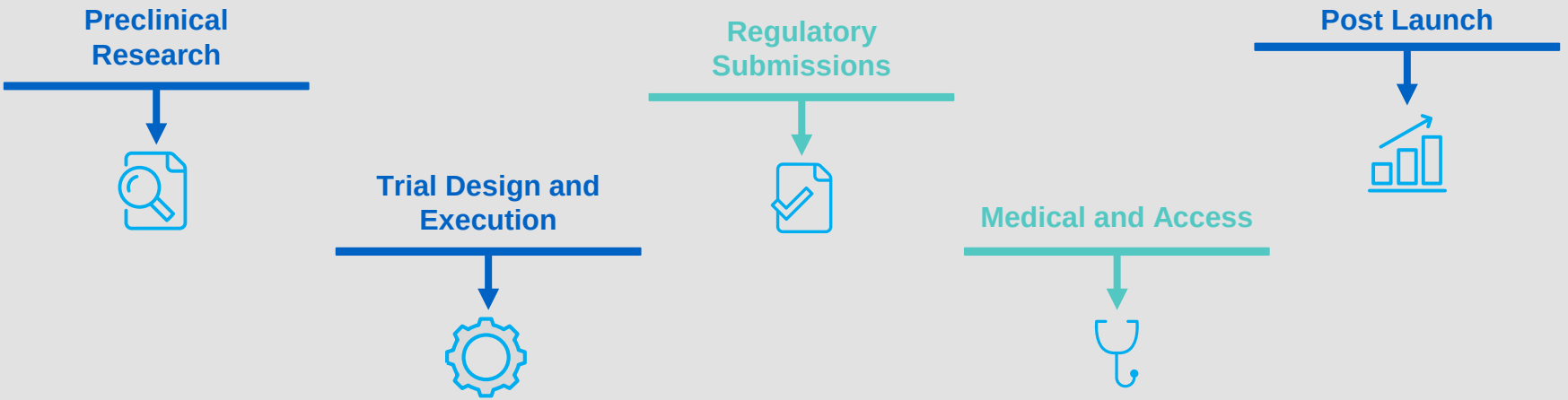
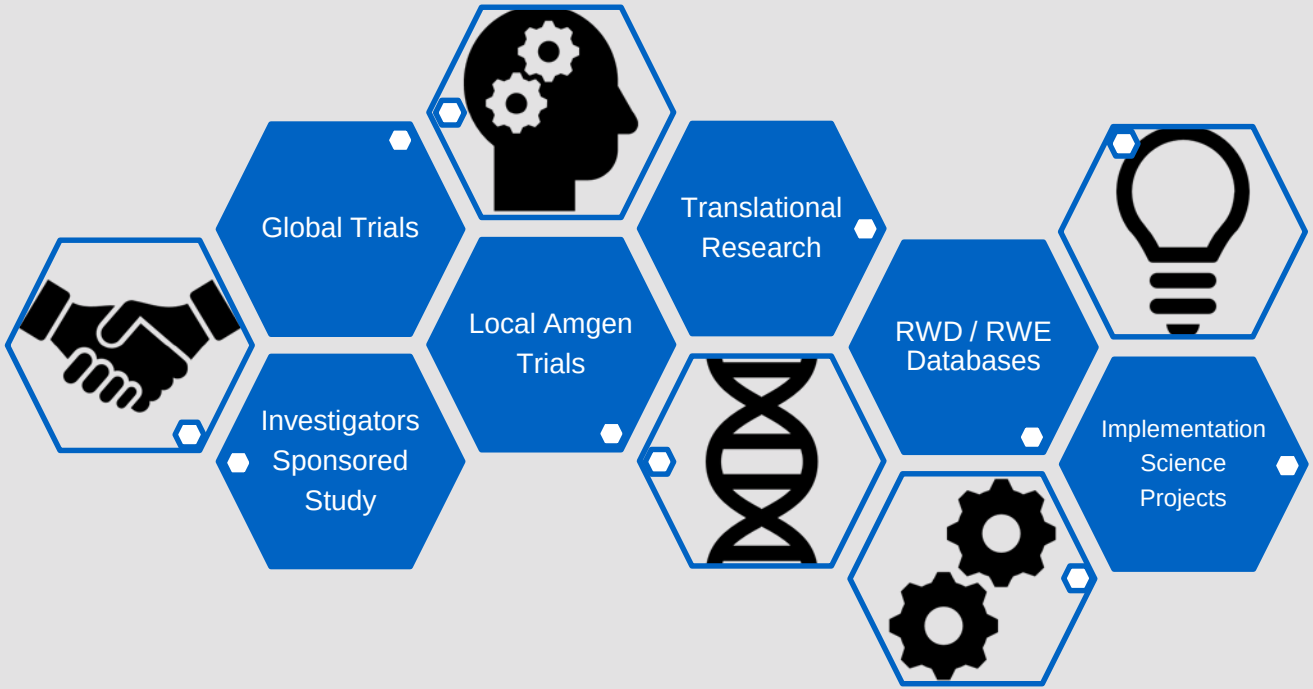
RWE SUPPORTS DEVELOPMENT OF NEW PRODUCTS AND INTEGRATION INTO PATIENT CARE



PARTNERSHIPS



CONCLUSION
PARTNERING ON CLINICAL TRIALS

- Oncology
- Early phases
- Complex trial designs
- Evidence supporting surrogates
- RWD / RWE
- Data to Transform the Health System
- **PATIENTS**

QUESTIONS

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