Software for Business Intelligence

BizInt Smart Charts

Patents & IP Sequences | Clinical Trials | Drug Pipelines

Examples -- BizInt Smart Strategy Dashboards (BizDash)

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Fall 2019

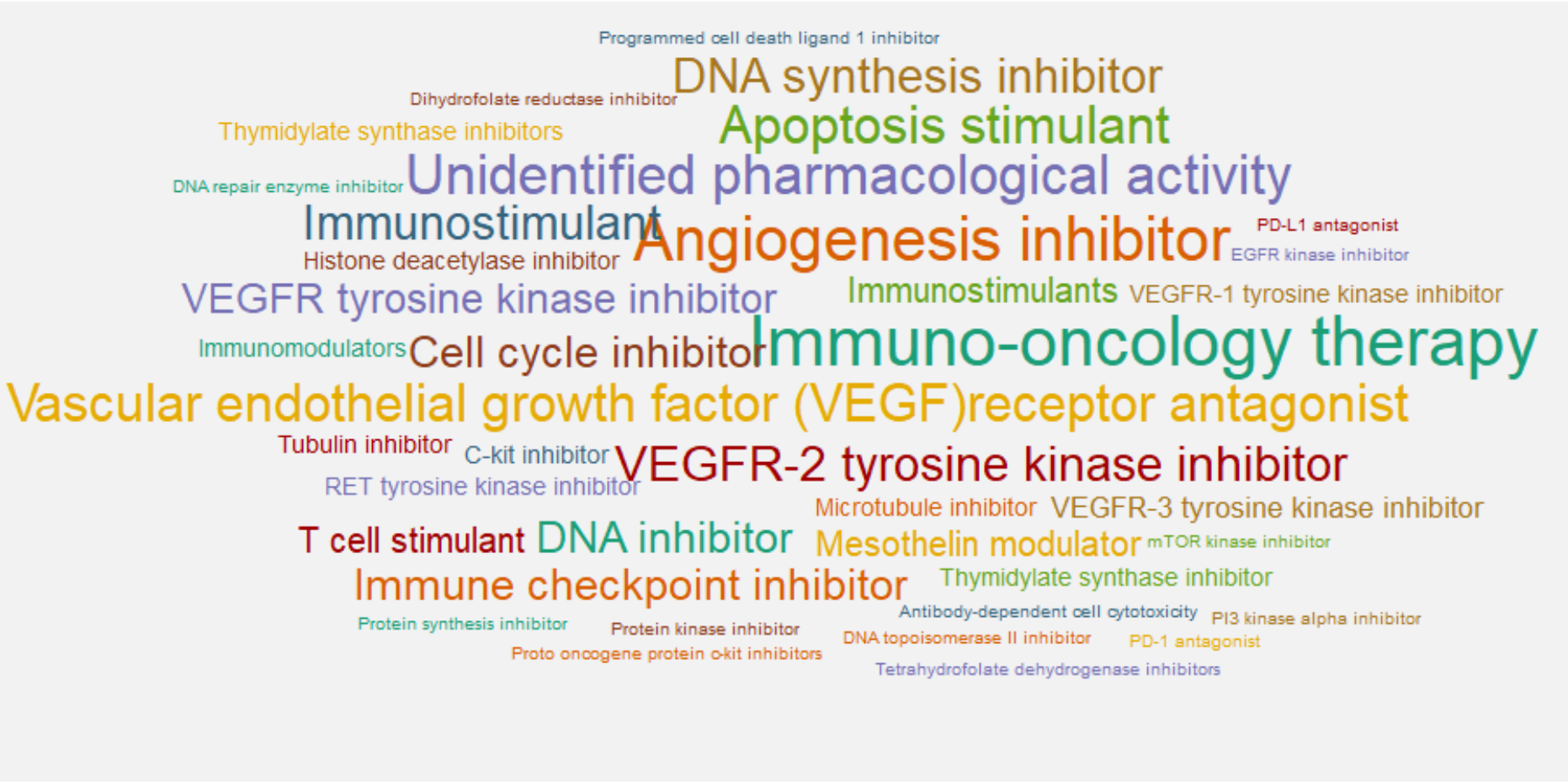
These slides provide examples of BizDash projects done over the past couple of years.

- Drug Pipeline landscapes: slides 3-20
- Clinical trial analysis: slides 21- 35
- Literature analysis (including KOL): slides 36-41
- *Note that in many cases the actual topic and data has been obscured.*

BizDash BizInt Smart Strategy Dashboards

Pipeline landscape:
Target novelty sneak peek

Target-based Action



Pipeline landscape:
Visualize a small pipeline or key drugs in a pipeline.

Merkel cell carcinoma drugs by indication phase - RoA

Biological Testing	Preclinical	Phase I	Phase II	Launched	Discontinued	No Development Reported
Merkel cell carcinoma therapies Vironika	**CK-301** TG Therapeutics	**BGB-A317** Celgene	**ALT 803** Altor BioScience Corporation	**avelumab** Merck KGaA	**lorvotuzumab mertansine** ImmunoGen	**ATN-161** Attenuon
	ETBX-051 NantWorks	**ID-G100** Immune Design	**cabozantinib S-malate** Exelixis			**tivantinib** ArQule
	ETBX-061 NantWorks	**pasireotide** Novartis	**CST-101** NantWorks			
	ipilimumab Bristol-Myers Squibb Co	**SIRPa-Fc** Trillium Therapeutics	**F16-IL2** Philogen			
	LTvax APCure	**utomilumab** Pfizer	**MCPyV vaccine** Fred Hutchinson Cancer Research Center			
	Merkel cell polyomavirus inhibitors Vironika		**nivolumab** Ono Pharmaceutical Co Ltd			
			pazopanib GlaxoSmithKline plc			
			pembrolizumab Merck & Co			
			PEN-221 Tarveda Therapeutics			
			sapanisertib Intellikine			
			talimogene laherparepvec BioVex Inc			
			tavokinogene telsaplasmid OncoSec Medical			

Route of Administration

- Injectable
- Injectable, intratumoral
- Oral
- Unknown

VP-SCE Piano Chart

Merkel cell carcinoma drugs by indication phase – type of molecule

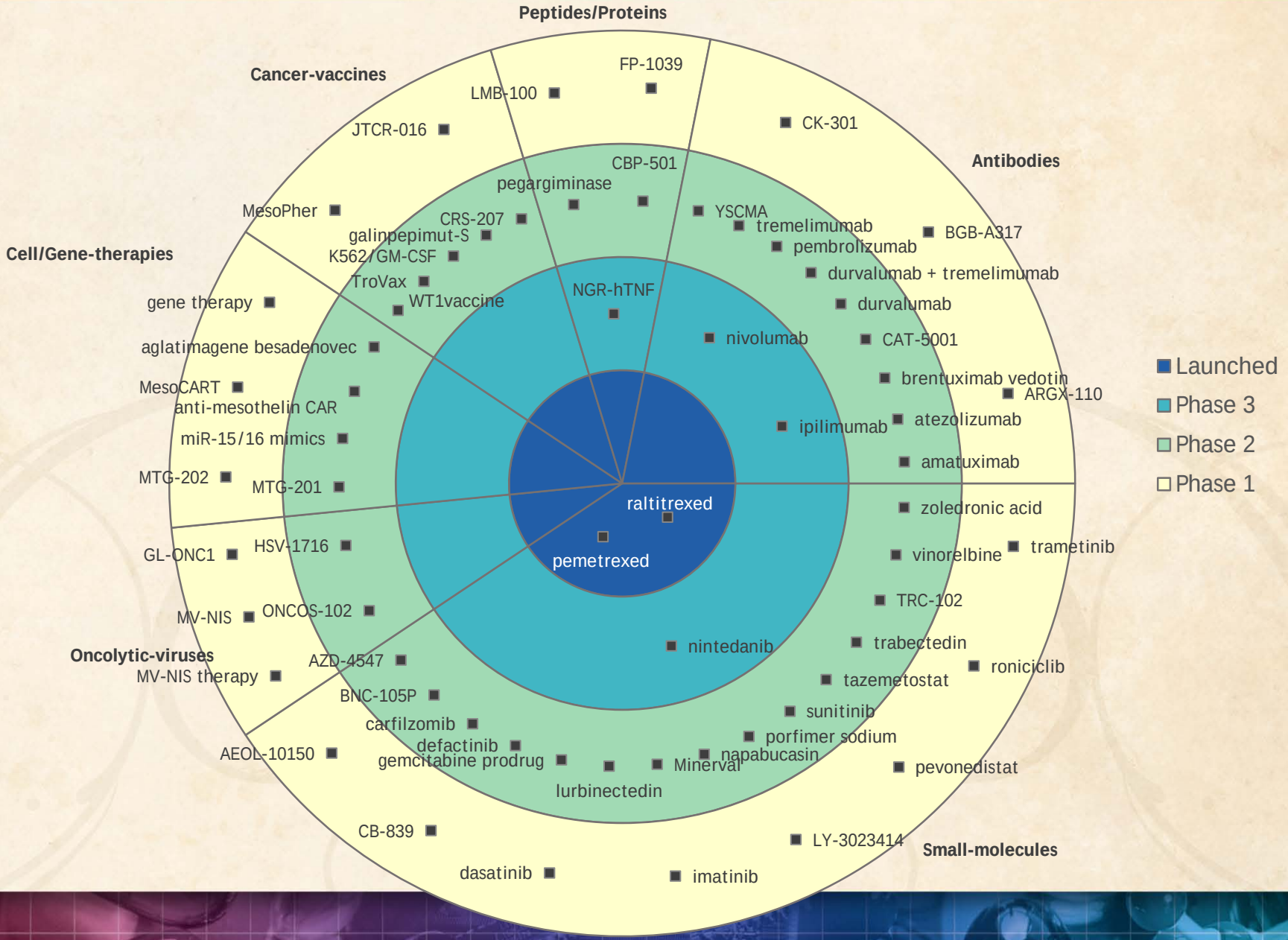
Biological Testing	Preclinical	Phase I	Phase II	Launched	Discontinued	No Development Reported
Merkel cell carcinoma therapies Vironika	**CK-301** TG Therapeutics	**BGB-A317** Celgene	**ALT 803** Altor BioScience Corporation	**avelumab** Merck KGaA	**lorvotuzumab mertansine** ImmunoGen	**ATN-161** Attenuon
	ETBX-051 NantWorks	**ID-G100** Immune Design	**cabozantinib S-malate** Exelixis			**tivantinib** ArQule
	ETBX-061 NantWorks	**pasireotide** Novartis	**CST-101** NantWorks			
	ipilimumab Bristol-Myers Squibb Co	**SIRPa-Fc** Trillium Therapeutics	**F16-IL2** Philogen			
	LTvax APCure	**utomilumab** Pfizer	**MCPyV vaccine** Fred Hutchinson Cancer Research Center			
	Merkel cell polyomavirus inhibitors Vironika		**nivolumab** Ono Pharmaceutical Co Ltd			
			pazopanib GlaxoSmithKline plc			
			pembrolizumab Merck & Co			
			PEN-221 Tarveda Therapeutics			
			sapanisertib Intellikine			
			talimogene laherparepvec BioVex Inc			
			tavokinogene telsaplasmid OncoSec Medical			

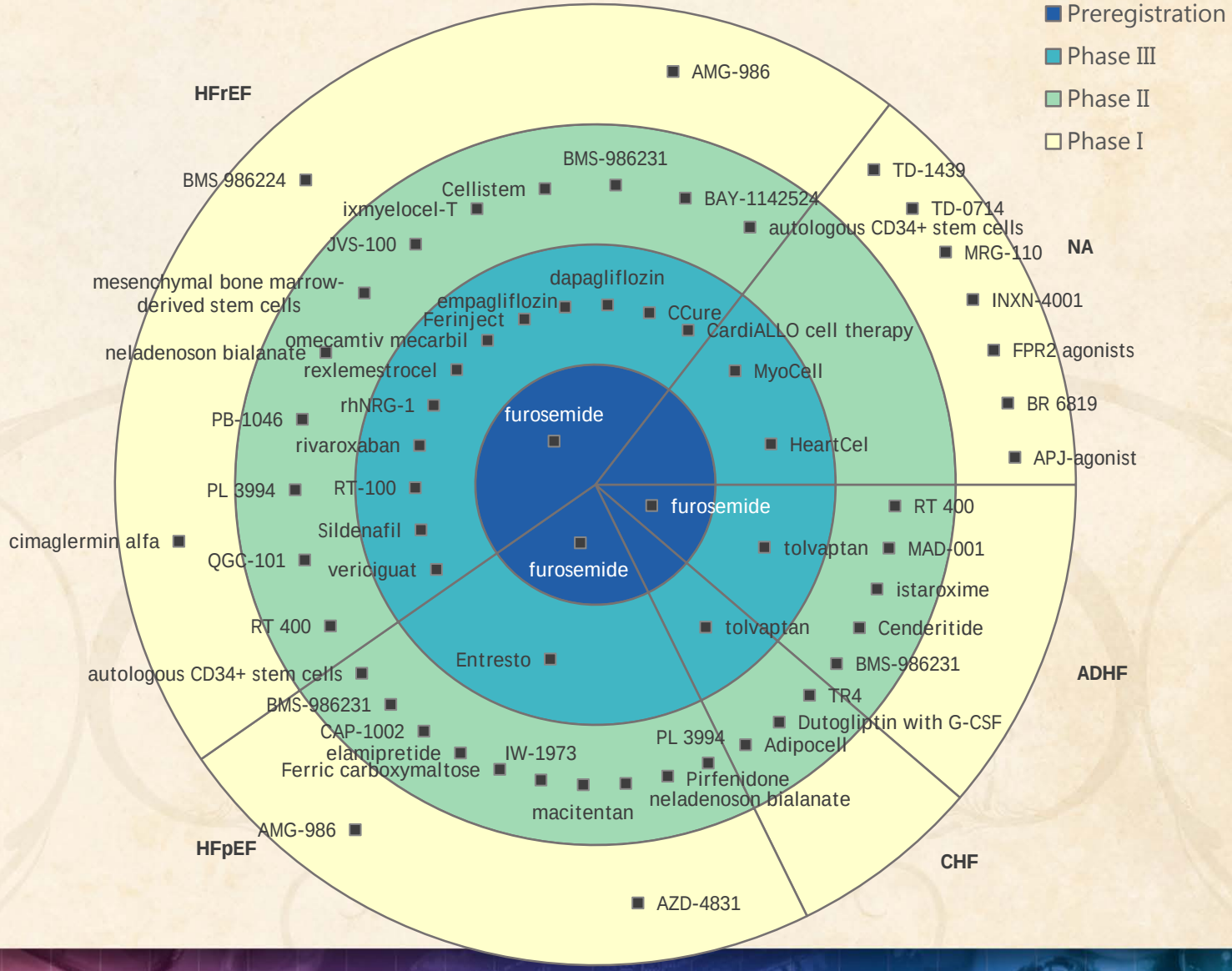
Type of molecule

- Antibody
- Biological, other
- Cell & gene therapy
- Protein & peptide
- Small molecule therapeutic
- Vaccine

VP-SCE Piano Chart

Pipeline landscape:
Visualize a larger pipeline or segment of a pipeline, emphasize phase progression (and attrition)


Peptides/Proteins
Antibodies
Small-molecules
Oncolytic-viruses
Cell/Gene-therapies
Cancer-vaccines
FP-1039
LMB-100
JTCR-016
CK-301
CBP-501
pegargiminase
MesoPher
CRS-207
galinpepimut-S
K562/GM-CSF
TroVax
WT1vaccine
gene therapy
aglatimagene besadenovec
MesoCART
anti-mesothelin CAR
miR-15/16 mimics
MTG-202
MTG-201
GL-ONC1
HSV-1716
MV-NIS
ONCOS-102
MV-NIS therapy
AZD-4547
BNC-105P
carfilzomib
AEOL-10150
defactinib
gemcitabine prodrug
lurbinectedin
CB-839
dasatinib
imatinib
Minerval
napabucasin
porfimer sodium
sunitinib
tazemetostat
trabectedin
nintedanib
TRC-102
vinorelbine
trametinib
zoledronic acid
pevonedistat
LY-3023414
raltitrexed
pemetrexed
NGR-hTNF
YSCMA
tremelimumab
pembrolizumab
BGB-A317
durvalumab + tremelimumab
durvalumab
nivolumab
CAT-5001
brentuximab vedotin
ARGX-110
ipilimumab
atezolizumab
amatuximab
roniciclib
Launched
Phase 3
Phase 2
Phase 1

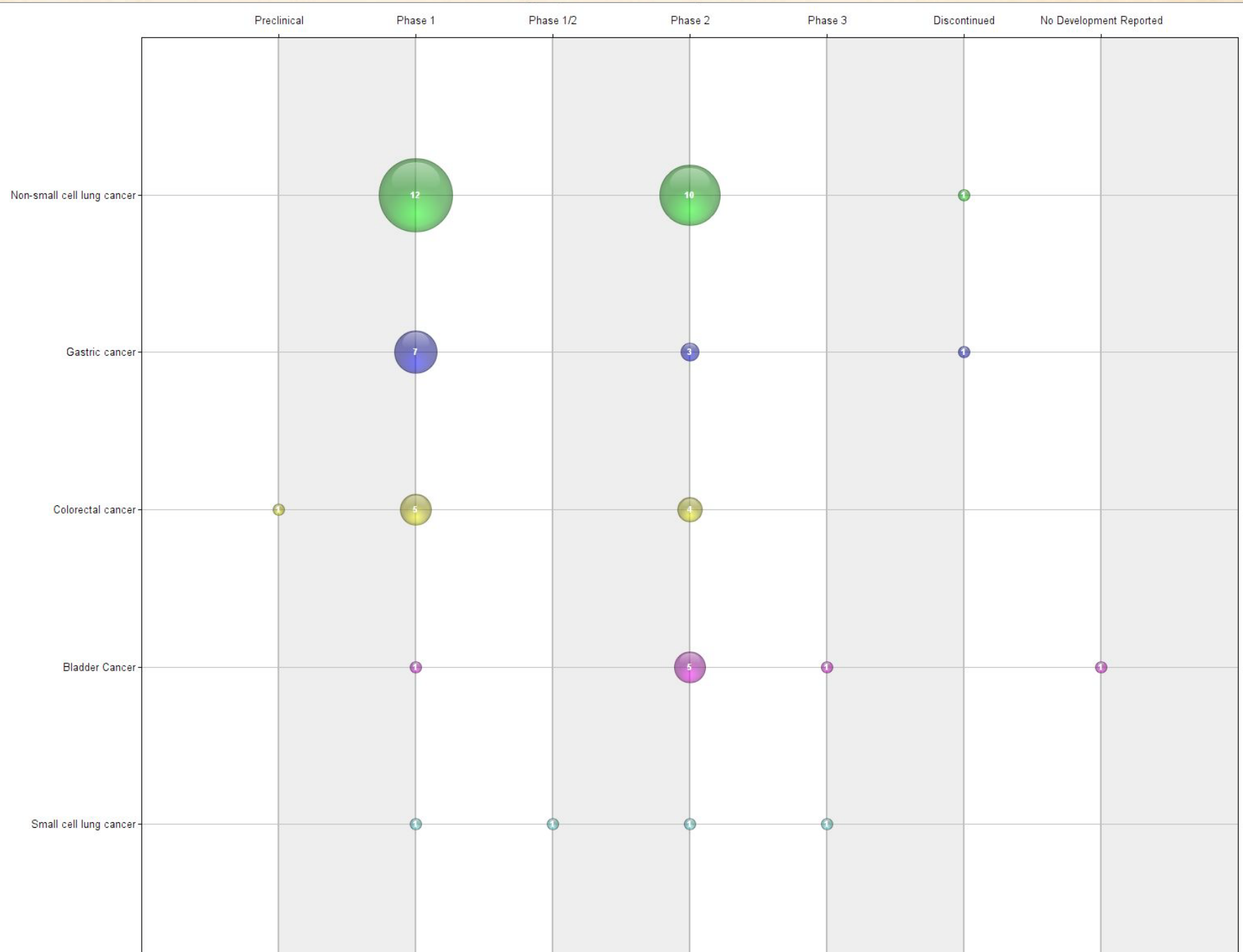

Preregistration
Phase III
Phase II
Phase I
HFrEF
AMG-986
BMS-986231
BMS 986224
Cellistem
BAY-1142524
ixmyelocel-T
JVS-100
dapagliflozin
mesenchymal bone marrow-derived stem cells
empagliflozin
Ferinject
CCure
omecamtiv mecarbil
CardiALLO cell therapy
neladenoson bialanate
rexlemestrocel
MyoCell
rhNRG-1
furosemide
PB-1046
rivaroxaban
HeartCel
PL 3994
RT-100
furosemide
Sildenafil
cimaglermin alfa
QGC-101
vericiguat
furosemide
RT 400
tolvaptan
Entresto
autologous CD34+ stem cells
BMS-986231
CAP-1002
elamipretide
IW-1973
Ferric carboxymaltose
macitentan
HFpEF
AMG-986
AZD-4831
TD-1439
TD-0714
autologous CD34+ stem cells
MRG-110
NA
INXN-4001
FPR2 agonists
BR 6819
APJ-agonist
RT 400
MAD-001
tolvaptan
istaroxime
Cenderitide
BMS-986231
TR4
Dutogliptin with G-CSF
PL 3994
Adipocell
Pirfenidone
neladenoson bialanate
ADHF
CHF

Pipeline landscape:
Compare the highest phase of development by indication

Highest Indications by phase, subtable and separate columns

	Drug	Highest Phase std	Extracted High Phases		Bladder Cancer High Phase	Colorectal Cancer High Phase	Gastric Cancer High Phase
			Indication (Cleaned)	Phase (1)			
1	sacituzumab govitecan	Preregistration	Bladder Cancer	Phase 2	Phase 2	Phase 2	Phase 2
			Cancer, breast	Preregistration			
			Cancer, cervical	Phase 2			
			Colorectal cancer	Phase 2			
			Cancer, endometrial	Phase 2			
			Gastric cancer	Phase 2			
			Cancer, head and neck	Phase 2			
			Cancer, liver	Phase 2			
			Non-small cell lung cancer	Phase 2			
			Small cell lung cancer	Phase 2			
			Cancer, oesophageal	Phase 2			
			Cancer, ovarian	Phase 2			
			Pancreatic cancer	Phase 2			
			Cancer, prostate	Phase 2			
			Cancer, renal	Phase 2			
			Cancer, solid, unspecified	Phase 2			
2	trastuzumab ADC, Synthon	Phase 3	Bladder Cancer	No Development Reported	No Development Reported		Phase 1
			Cancer, breast	Phase 3			
			Cancer, endometrial	No Development Reported			
			Gastric cancer	Phase 1			
			Cancer, lung, unspecified	No Development Reported			
			Cancer, solid, unspecified	Phase 1			
3	rovalpituzumab tesirine	Phase 3	Cancer, brain	Phase 2			Phase 2
			Gastric cancer	Phase 2			
			Small cell lung cancer	Phase 3			
			Cancer, melanoma	Phase 2			
			Cancer, neuroendocrine, unspecified	Phase 2			
			Cancer, pancreatic, neuroendocrine	Phase 2			
			Cancer, prostate, neuroendocrine	Phase 2			
			Cancer, solid, unspecified	Phase 2			
			Cancer, thyroid	Phase 2			

TA landscape – Indications by highest phase in that indication



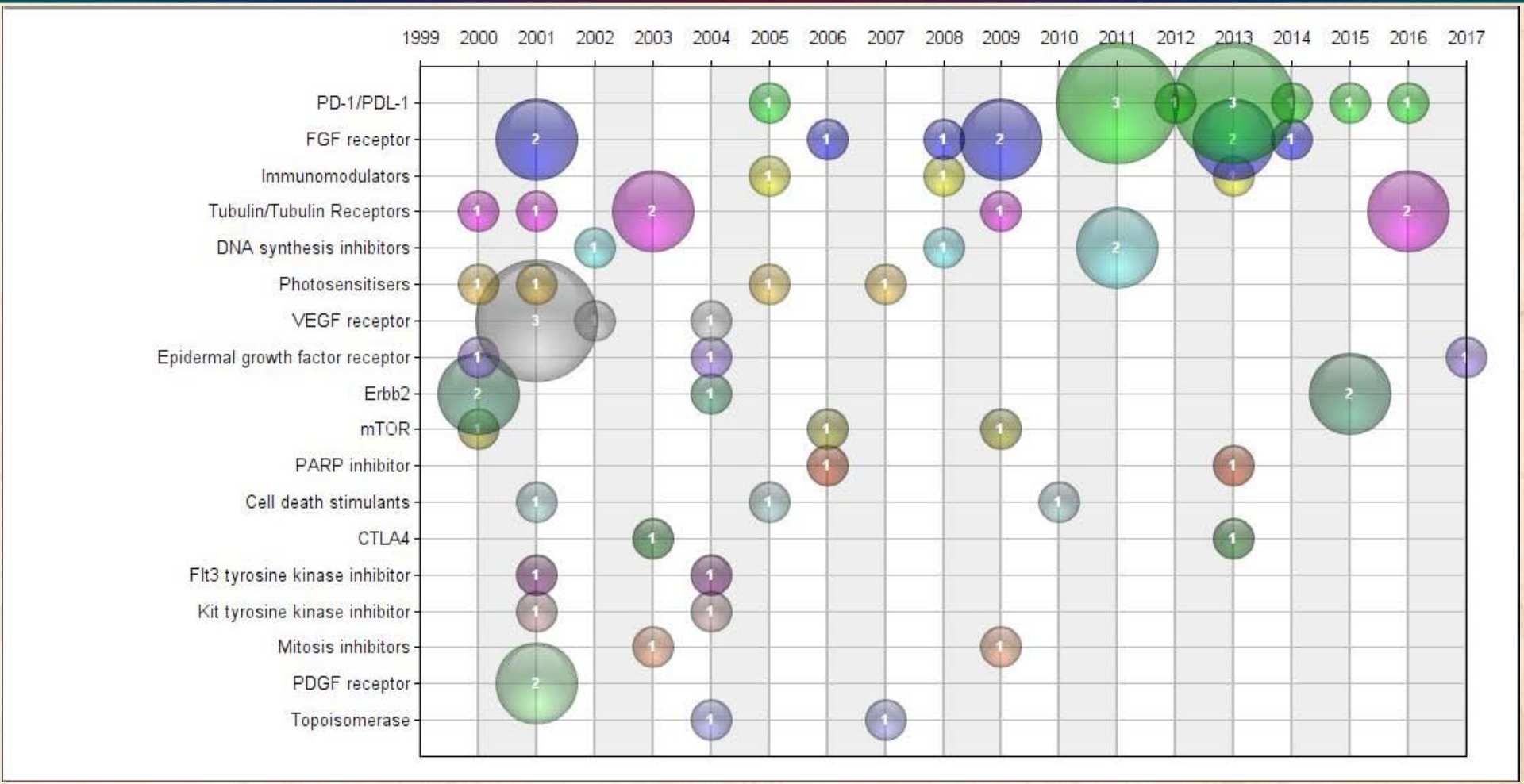
Pipeline landscape:
What are the top mechanisms of action in this area?

Pipeline landscape:

What are the top mechanisms of action over time?

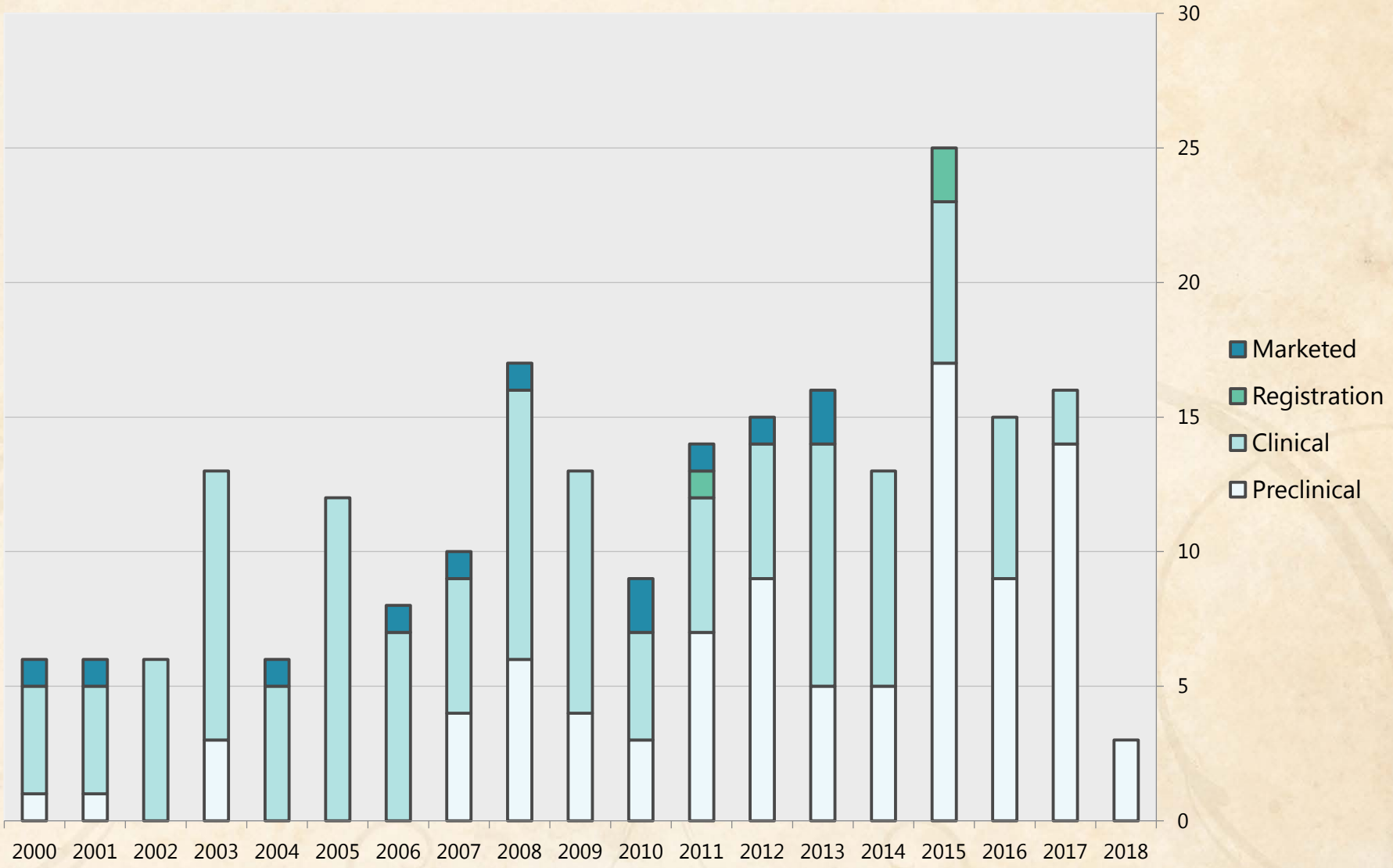
- VP-SCE: Extract the earliest date from each drug record
- Reference Rows: Select the earliest date associated with each drug
- VP-SCE: Visualize MoA trends over time

Top Drug Targets vs earliest pipeline date 2000-2017



Pipeline landscape:
Drug landscape by earliest date identified and phase.
What are the trends in when drugs in this area are first identified in the pipeline?

Drugs in development by earliest year identified (2000-2018) and current indication phase

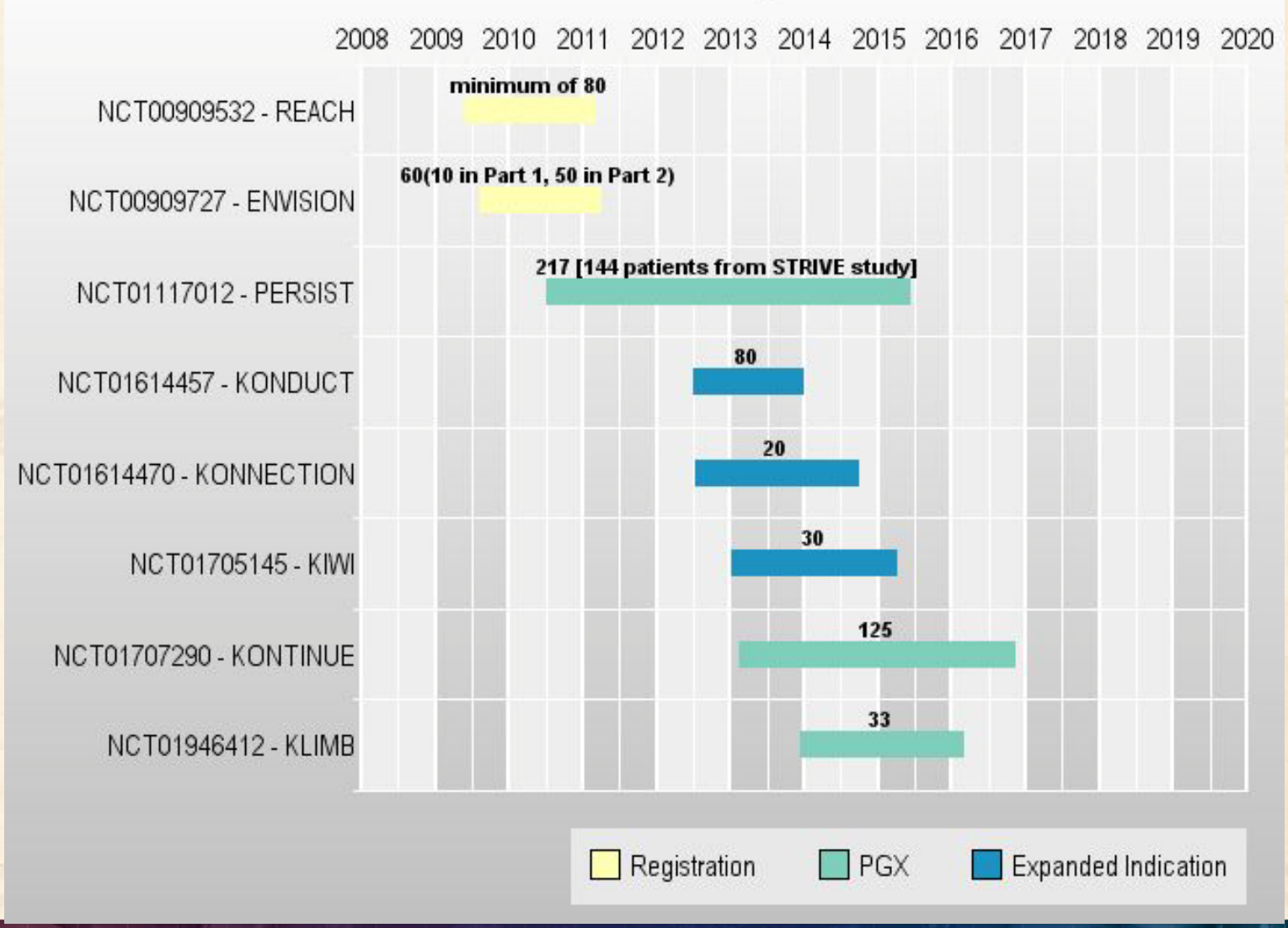


Pipeline landscape:
Extract the earliest date for each phase for each drug to review development timing

	Product	Database	Originator	Highest Phase	Earliest Date by Phase					
					Preclin	Ph 1	Ph 2	Ph 3	Reg	Launch
1.	PreFluCel 1.1 CORTL	1.1 CORTL | link 1.2 Adis | link	Baxter International 1.2 Adis	Marketed 1.2 Adis	1998-04-30		2007-01-16	2007-11-26	2002-03-10	2010-09-30 1.1 CORTL
2.	H1N1 pandemic influenza vaccine (AS03 adjuvanted) 1, GlaxoSmithKline 2.1 CORTL	2.1 CORTL | link	GlaxoSmithKline plc 2.1 CORTL	Launched 2.1 CORTL	2009-04-30		2009-08-19	2009-07-21	2009-09-29	2009-10-15 2.1 CORTL
3.	Aflunov 3.1 Adis	3.1 Adis | link	Novartis Novartis Vaccines 3.1 Adis	Marketed 3.1 Adis	2004-05-28		2007-03-30	2014-04-15	2011-03-16	2011-08-11 3.1 Adis
4.	Inflexal V 4.1 CORTL	4.1 CORTL | link 4.2 Adis | link	Berna Biotech 4.2 Adis	Market Withdrawal 4.2 Adis	2007-03-21		1996-03-20	2012-12-30	2001-12-17	 4.1 CORTL
5.	Pandemrix™ 5.1 Adis	5.1 Adis | link	GlaxoSmithKline 5.1 Adis	Marketed 5.1 Adis	2009-06-16	2009-08-24	2009-09-17	2009-09-17	2009-09-30	2009-10-27 5.1 Adis
6.	Vepacel™ 6.1 Adis	6.1 Adis | link	Baxter International 6.1 Adis	Marketed 6.1 Adis	2006-05-12	2008-06-11	2007-09-30	2007-04-30	2009-12-17	2015-03-19 6.1 Adis
7.	Prepandrix™ 7.1 CORTL	7.1 CORTL | link 7.2 Adis | link	GlaxoSmithKline 7.2 Adis	Marketed 7.2 Adis		2006-04-04	2007-02-28	2006-03-30	2008-05-15	2009-04-30 7.1 CORTL
8.	FLUVAL AB 8.1 CORTL	8.1 CORTL | link	Omninvest 8.1 CORTL	Launched 8.1 CORTL					1997-12-31	1998-01-01 8.1 CORTL
9.	Influenza A virus vaccine H5N2 intranasal - BioDiem 9.1 Adis	9.1 Adis | link	Institute of Experimental Medicine of the Russian Academy of Medical Sciences 9.1 Adis	Marketed 9.1 Adis	2006-08-30	2012-05-01	2007-09-30			2012-12-01 9.1 Adis
10.	Grippol TC 10.1 CORTL	10.1 CORTL | link 10.2 Adis | link	Solvay SA 10.1 CORTL	Launched 10.1 CORTL	2004-11-17			2008-10-01	2009-09-09	2011-11-25 10.1 CORTL

Clinical trials:
Characterize trials by key factors (duration, acronym, enrollment, trial type)

NCT Number - Acronym Timeline



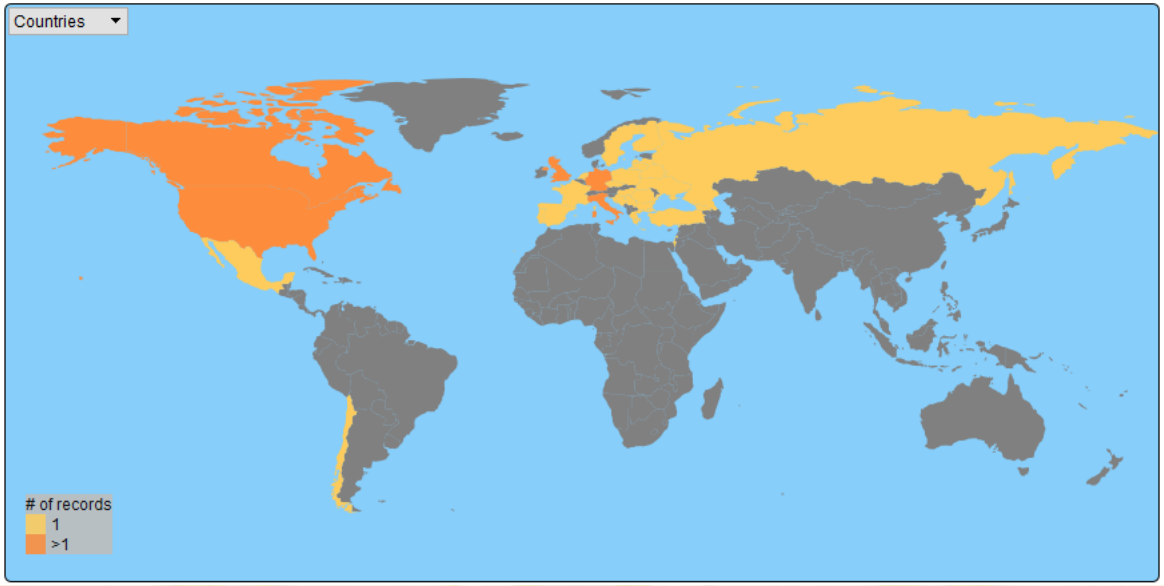
Clinical trials:
Extract primary endpoint terms from trial registries

Chart with endpoint terms extracted and normalized with VP-SCE

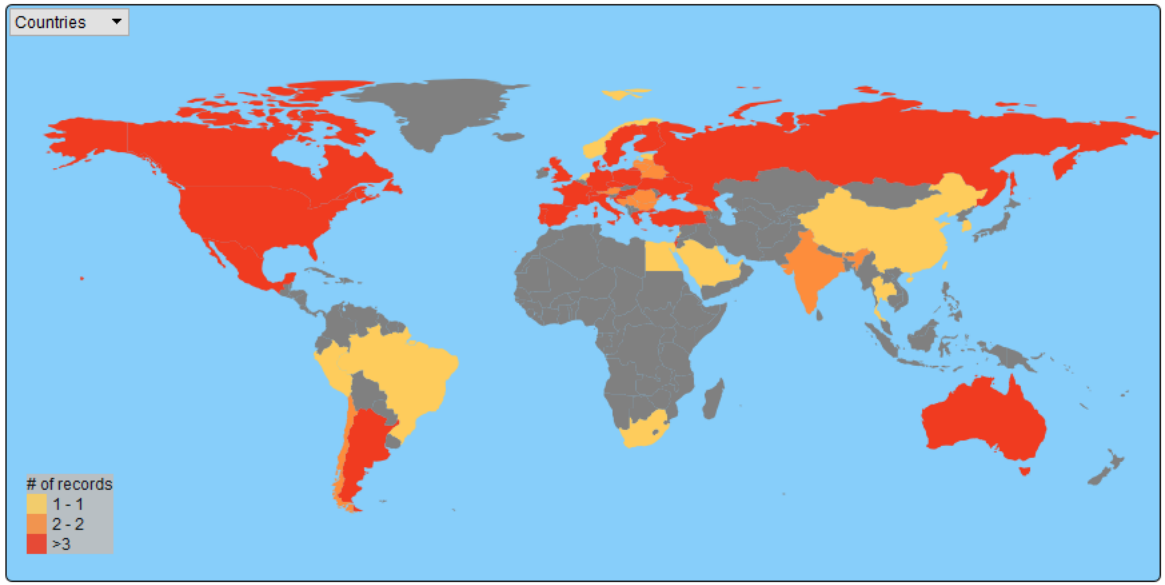
	Trial Title	Database	Common Trial ID	Primary Outcome	Primary Outcome : extracted endpoints	Phase	Sponsor(s)
1.	A Randomized, Double-Blind, Placebo-Controlled, Parallel Group Design Study to Evaluate the Efficacy and Safety of Teriflunomide in Reducing the Frequency of Relapses and Delaying the Accumulation of Physical Disability in Subjects With Multiple Sclerosis With Relapses 1.1 NCT	1.1 NCT | link 1.2 EUDRACT | link 1.3 EUDRACT | link 1.4 EUDRACT | link 1.5 EUDRACT | link 1.6 EUDRACT | link 1.7 EUDRACT | link 1.8 EUDRACT | link 1.9 EUDRACT | link 1.10 EUDRACT | link	NCT00134563	Annualized Relapse Rate [ARR]: Poisson Regression Estimates - ARR is obtained from the total number of confirmed relapses that occured during the treatment period divided by the sum of the treatment durations. Each episode of relapse - appearance, or worsening of a clinical symptom that was stable for at least 30 days, that persisted for a minimum of 24 hours in the absence of fever - was to be confirmed by an increase in EDSS score or Functional System scores. To account for the different treatment durations among participants, a Poisson regression model with robust error variance was used (total number of confirmed relapses as response variable; log-transformed treatment duration as "offset" variable; treatment group, region of enrollment and baseline EDSS stratum as covariates). 1.1 NCT	EDSS relapse rate 1.1 NCT	Phase 3 1.1 NCT	Sanofi 1.1 NCT
2.	Clinical Study Protocol: Evaluation of the Efficiency of Ritalin in Multiple Sclerosis Patients 2.1 NCT	2.1 NCT | link	NCT00220493	Score on the Paced Auditory Serial Addition Test (PASAT) one hour after taking the drug/placebo 2.1 NCT	PASAT 2.1 NCT	Phase 1 2.1 NCT	Sheba Medical Center 2.1 NCT
3.	A Randomised Controlled Trial of Neuroprotection With Lamotrigine in Secondary Progressive Multiple Sclerosis: Single Centre, Phase 2 Trial 3.1 NCT	3.1 NCT | link 3.2 EUDRACT | link	NCT00257855	Change in central brain volume on MRI using the 'Loseff method' 3.1 NCT	brain volume 3.1 NCT	Phase 2 3.1 NCT	University College London Hospitals 3.1 NCT
4.	Phase 1 Safety Study of RTL1000 (Recombinant T Cell Receptor Ligand) in Subjects With Multiple Sclerosis 4.1 NCT	4.1 NCT | link	NCT00411723	Adverse events, safety, laboratory parameters, vital signs, ECG and physical exam results. Disease parameters (neurologic exam, EDSS, 25 foot timed walk, 9-hole PEG test, MRI). Antibodies to drug. 4.1 NCT	9HPT AEs EDSS safety 4.1 NCT	Phase 1 4.1 NCT	Artielle ImmunoTherapeutics 4.1 NCT
5.	A Double-blind, Randomized, Multicenter, Placebo-controlled, Parallel-group Study Comparing the Efficacy and Safety of 0.5mg Fingolimod Administered Orally Once Daily Versus Placebo in Patients With Primary Progressive Multiple Sclerosis and An Open-label, Single-arm Extension Study to the Double-blind, Randomized, Multicenter, Placebo-controlled, Parallel-group Study Comparing the Efficacy and Safety of0.5 mg FTY720 Administered Orally Once Daily Versus Placebo in Patients With Primary Progressive Multiple Sclerosis 5.1 NCT	5.1 NCT | link 5.2 EUDRACT | link 5.3 EUDRACT | link 5.4 EUDRACT | link 5.5 EUDRACT | link 5.6 EUDRACT | link 5.7 EUDRACT | link 5.8 EUDRACT | link 5.9 EUDRACT | link 5.10 EUDRACT | link 5.11 EUDRACT | link 5.12 EUDRACT | link 5.13 EUDRACT | link	NCT00731692	Kaplan-Meier Estimate of the Risk of 3-month Confirmed Disability Progression Based on Composite Endpoint - 3-month sustained increase from Baseline in EDSS (at least 1 point increase from Baseline for patients with a Baseline value of 5 or less or at least 0.5 point increase from Baseline for patients with a Baseline value of 5.5 or more) or 3-month sustained increase of at least 20% from BL in the time taken to complete the timed 25-foot walk test (25' TWT); or 3-month sustained increase of at least 20% from BL in the time taken to complete the 9-HPT. The 25' TWT is a quantitative measure of lower extremity function. The EDSS is a scale assessing neurologic impairment, including a series of scores in each of 8 functional systems: Visual, Brain Stem, Pyramidal, Cerebellar, Sensory, Bowel and Bladder, Cerebral and Other functions. The score ranges from 0 (normal) to 10 (death due to MS)). The 9-hole peg test (9-HPT) is a quantitative measure of upper extremity (arm and hand) function. 5.1 NCT	9HPT disease progression EDSS 5.1 NCT	Phase 3 5.1 NCT	Novartis Pharmaceuticals 5.1 NCT

Where Are Endpoints Being Tested?

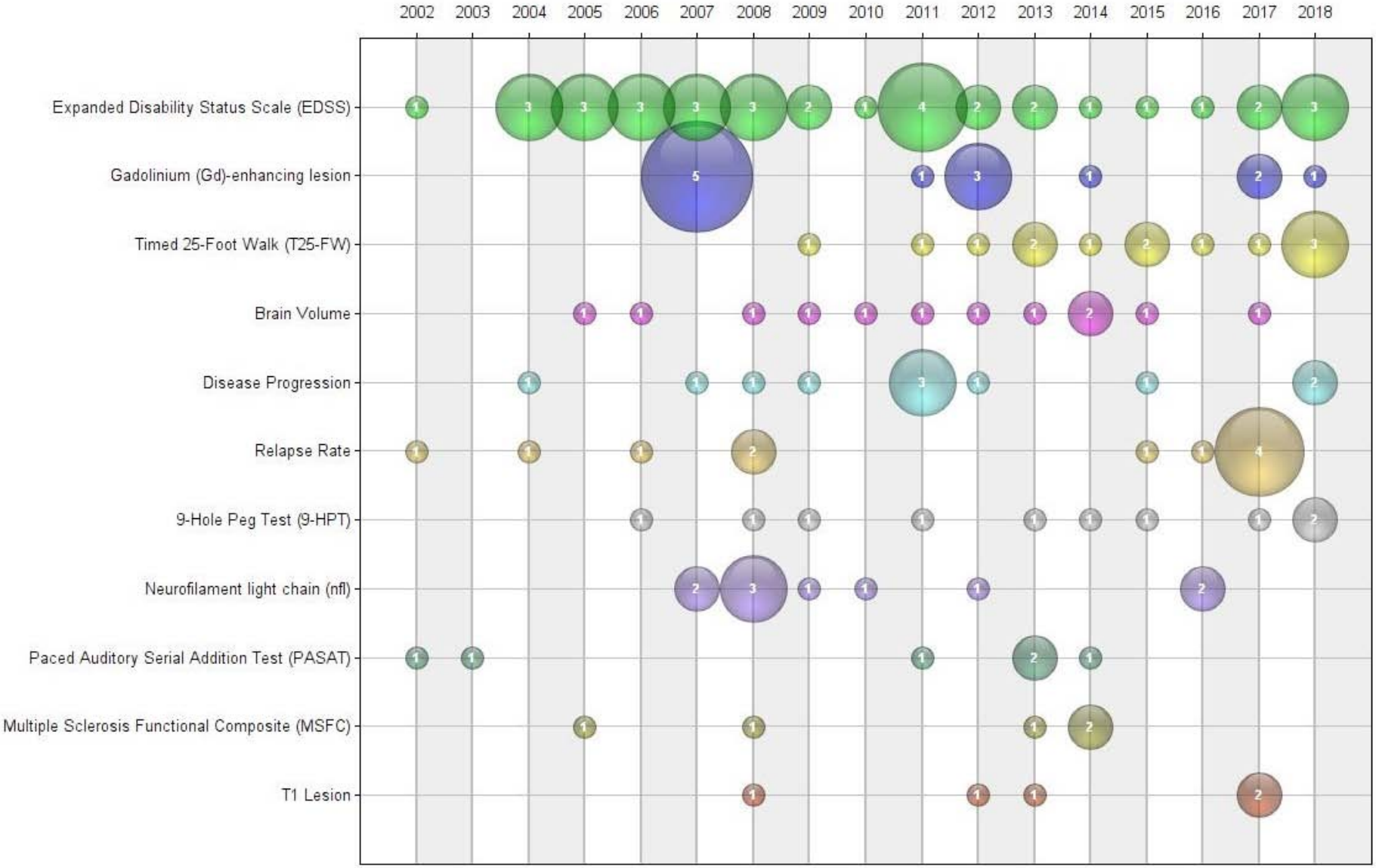
Progressive MS Trials with brain volume/atrophy endpoints (US+EU registries)



Progressive MS Trials with relapse rate endpoints (US+EU registries)

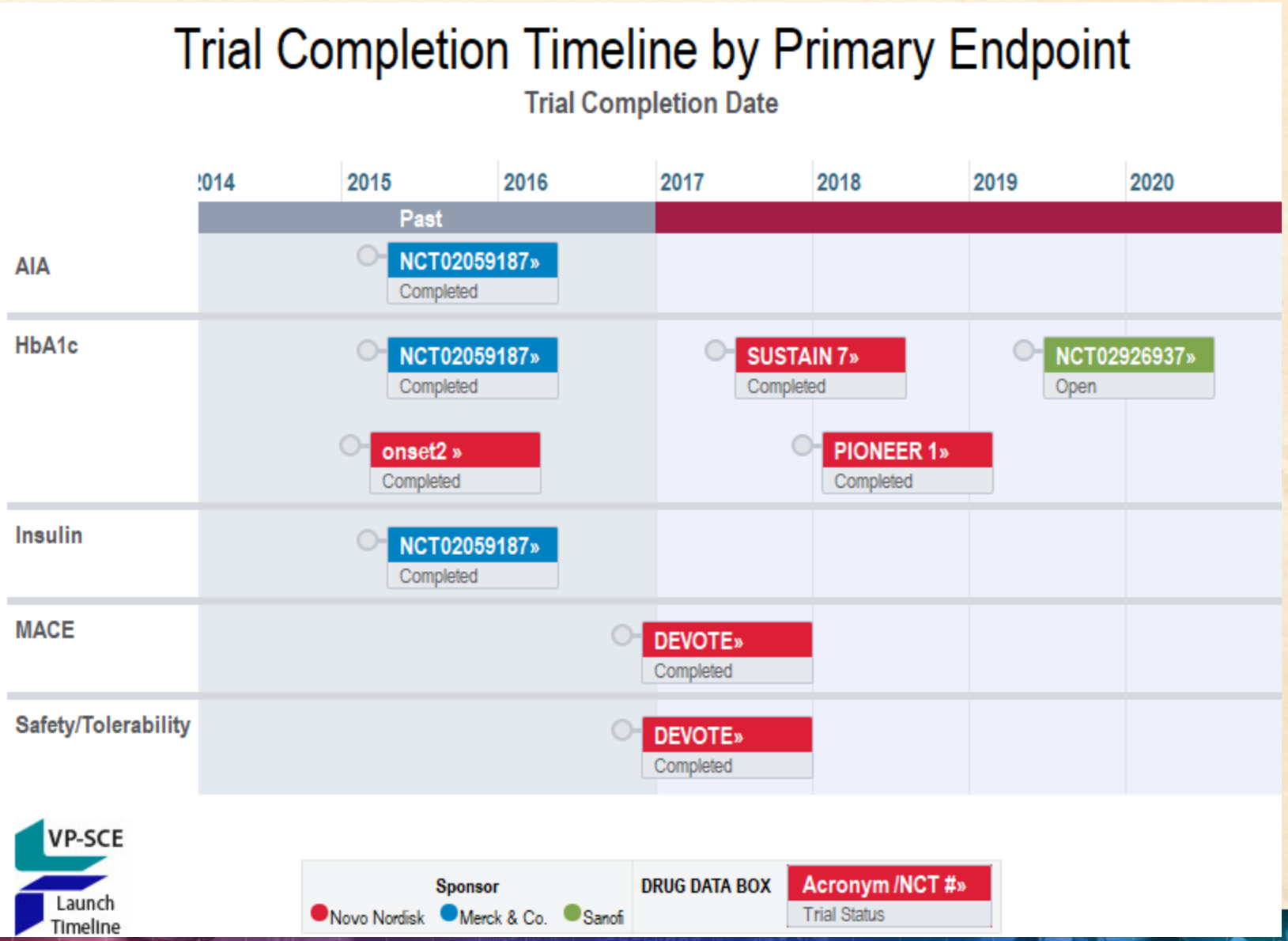


How Do Endpoints Evolve Over Time? Primary Endpoints by Trial Start Year (US+EU registries)

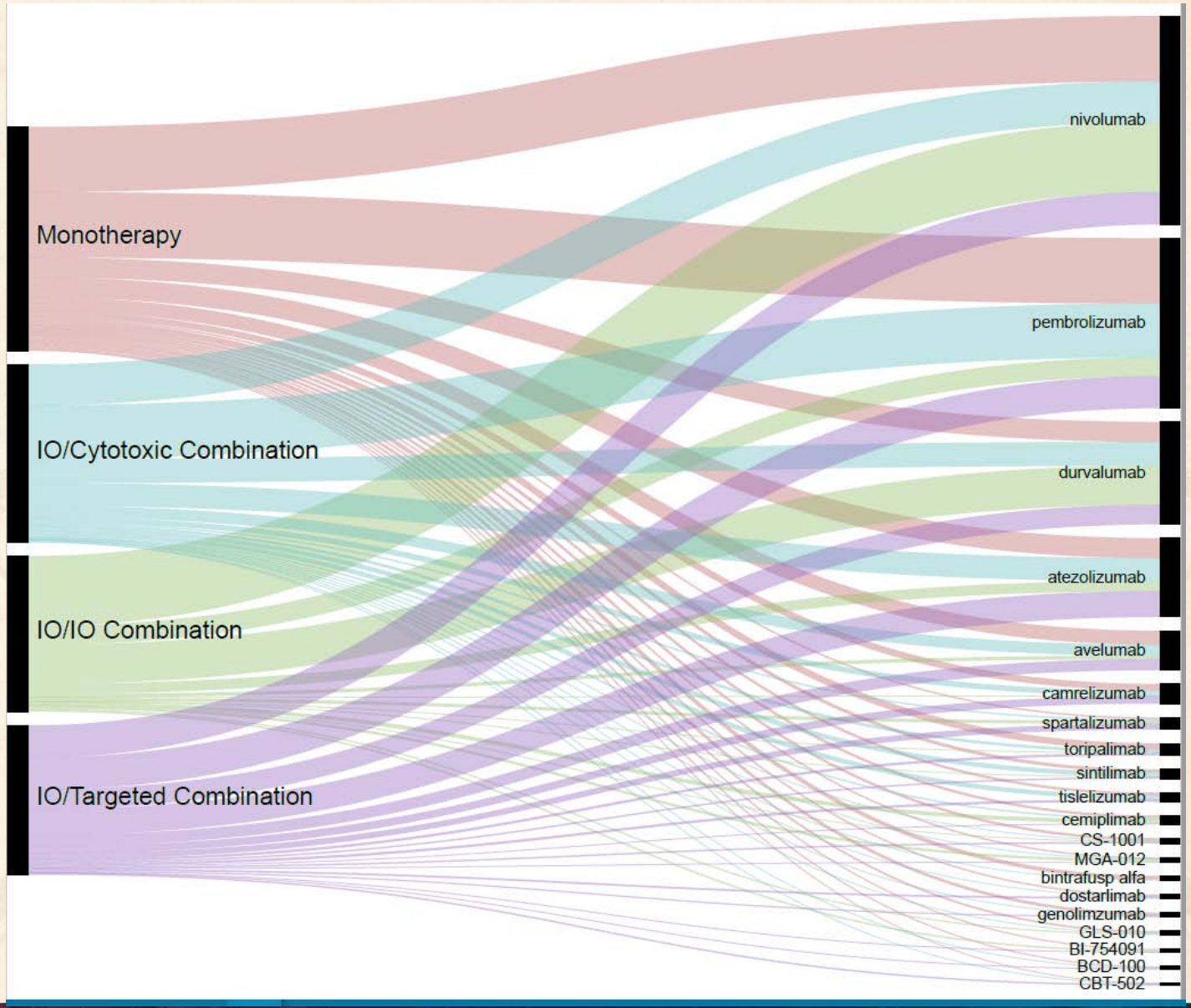


Clinical trials:
Characterize trials by primary endpoints

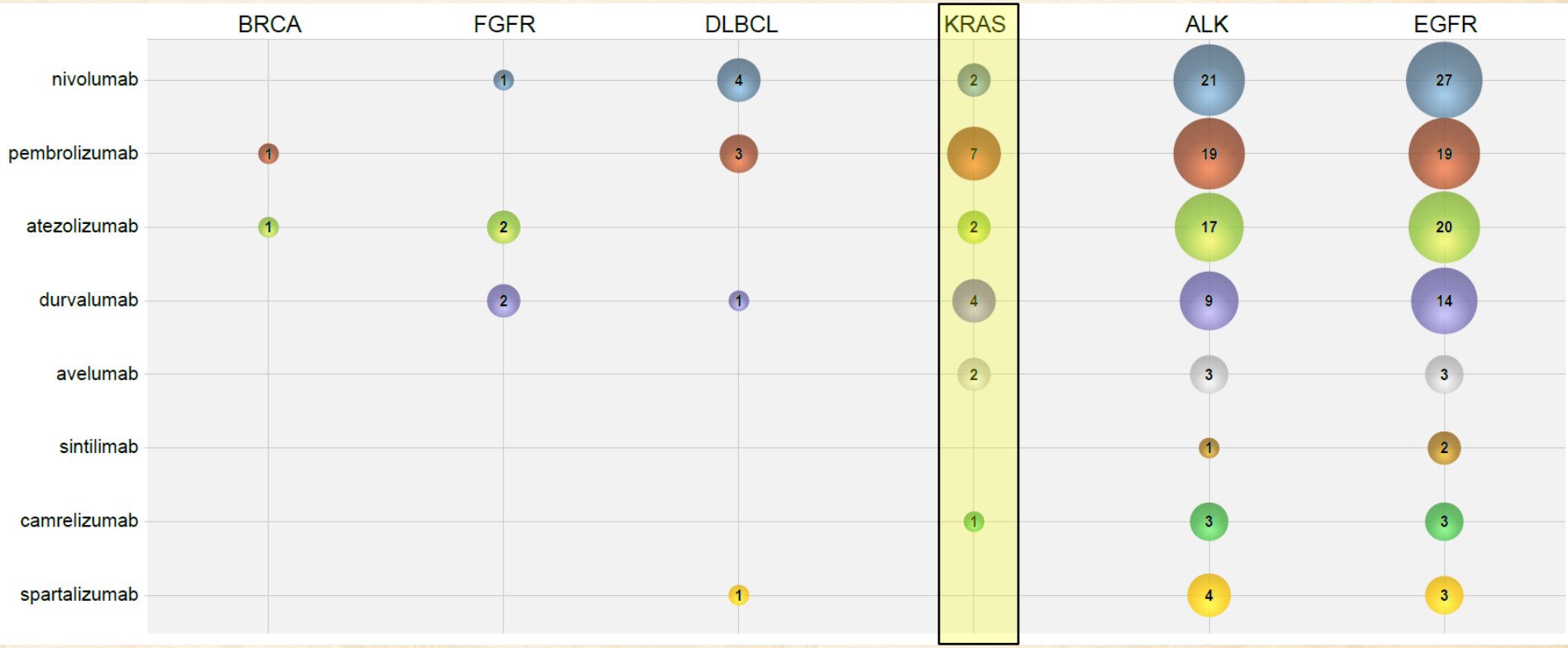
Trial Completion Timeline by Primary Endpoint



Clinical trials:
Combination drugs - Identify new partners

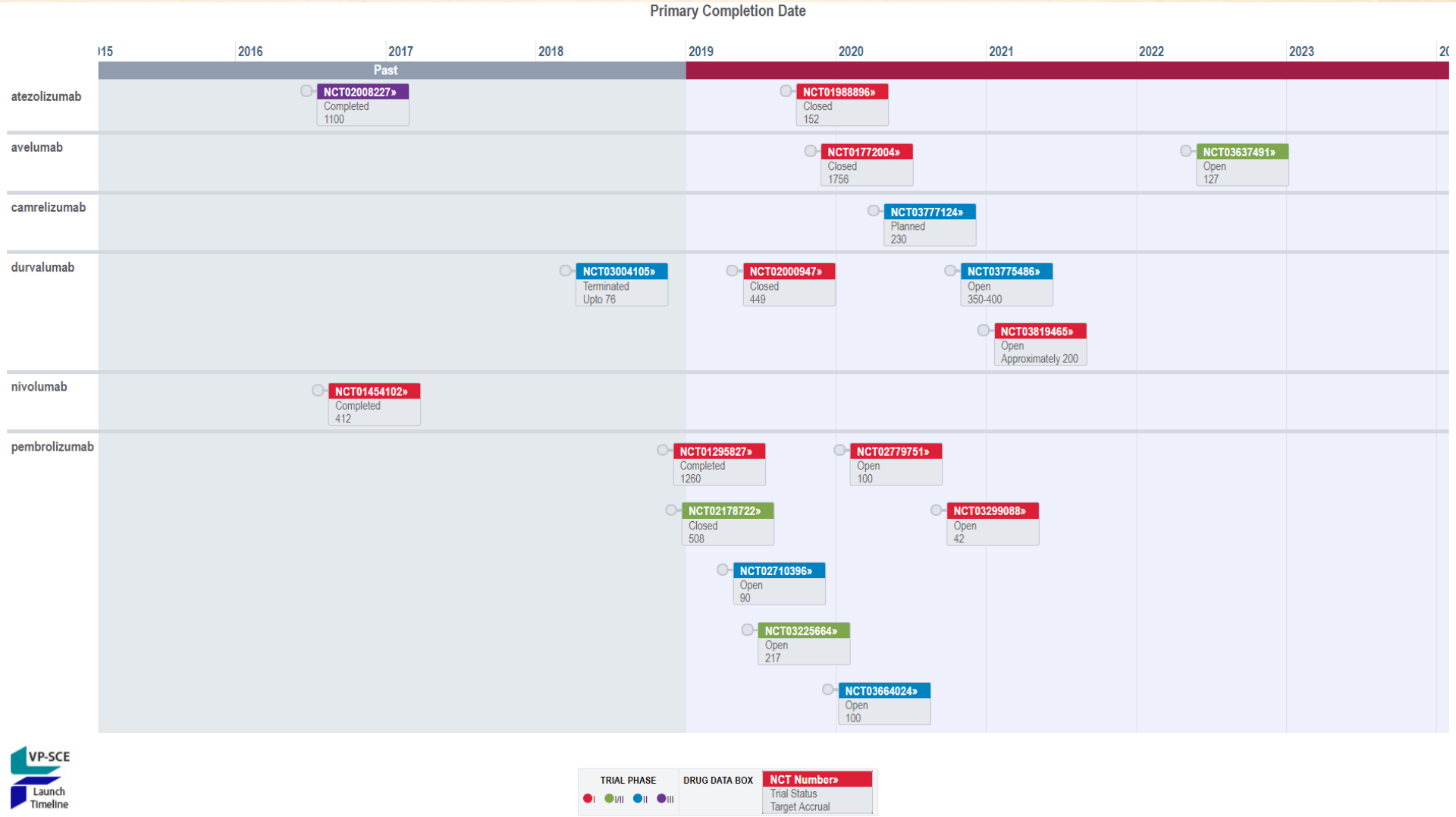


Clinical trials:
Identify new biomarkers for competitive differentation



Review the trials for a single biomarker to assess competitor strategy

Trials for a single biomarker to assess competitor strategy



Trials for a single biomarker to assess competitor strategy

Citeline TrialTrove: PD-1/PD-L1 KRAS Trials

	Trial Title	Primary Drugs - PD1	Primary Drugs	Trial Phase	Trial Status	Target Accrual	Start Date	Primary Completion Date	Trial Tags
1	A Phase III, Open-Label, Multicenter, Randomized Study to Investigate the Efficacy and Safety of Atezolizumab (Anti-PD-L1 Antibody) Compared With Docetaxel in Patients With Non-Small Cell Lung Cancer After Failure With Platinum Containing Chemotherapy	atezolizumab	atezolizumab	III	Completed	1100	2014-03-11 (Actual)	2016-06-22 (Actual)	Expanded Indication PGX - Patient Preselection/Stratification
2	A Phase Ib Study of the Safety and Pharmacology of Atezolizumab Administered With Cobimetinib in Patients With Locally Advanced or Metastatic Solid Tumors	atezolizumab	cobimetinib (oral tablet) atezolizumab	I	Closed	152	2013-12-27 (Actual)	2019-09-01 (Anticipated)	Biomarker/Efficacy IO/Targeted Combination PGX - Patient Preselection/Stratification
3	A Phase Ib/II Study To Evaluate Safety And Clinical Activity Of Avelumab In Combination With Binimetinib With Or Without Talazoparib In Patients With Locally Advanced Or Metastatic Ras-mutant Solid Tumors	avelumab	binimetinib talazoparib avelumab	I/II	Open	127	2018-08-15 (Actual)	2022-05-01 (Anticipated)	Biomarker/Efficacy IO/Targeted Combination PGX - Biomarker Identification/Evaluation PGX - Patient Preselection/Stratification
4	A Phase I, Open-label, Multiple-ascending Dose Trial to Investigate the Safety, Tolerability, Pharmacokinetics, Biological and Clinical Activity of Avelumab (MSB0010718C) in Subjects With Metastatic or Locally Advanced Solid Tumors and Expansion to Selected Indications	avelumab	avelumab	I	Closed	1756	2013-01-31 (Actual)	2019-10-31 (Anticipated)	Biomarker/Efficacy Expanded Indication PGX - Patient Preselection/Stratification
5	Phase II Study of SHR-1210(Anti-PD-1 Antibody) Combination With Apatinib Versus Pemetrexed and Carboplatin in Subjects With KRAS Mutant Stage IV Non-squamous Non-small Cell Lung Cancer	camrelizumab	apatinib camrelizumab	II	Planned	230	2019-02-01 (Anticipated)	2020-04-01 (Anticipated)	IO/Targeted Combination PGX - Patient Preselection/Stratification

Literature:
Analyze literature and clinical trials to create metrics for Key Opinion Leader assessment

	Title	Author (Cleaned) :30+	Corporate Source	Corporate Source: Region	Source	DOI
1	Robotic pancreaticoduodenectomy in the presence of aberrant or anomalous hepatic arterial anatomy: safety and oncologic outcomes.	Zeh, Herbert J	Division of Gastrointestinal Surgical Oncology, Department of Surgery, University of Pittsburgh Medical Center, Pittsburgh, PA, USA.	North America	HPB : the official journal of the International Hepato Pancreato Biliary Association (2015), vol. 17, no. 7, p. 594-9.	10.1111/hpb.12414
2	Serum CA 19-9 response to neoadjuvant therapy is associated with outcome in pancreatic adenocarcinoma.	Zeh, Herbert J	Department of Surgery, University of Pittsburgh, Pittsburgh, PA, USA.	North America	Annals of surgical oncology (2014), vol. 21, no. 13, p. 4351-8.	10.1245/s10434-014-3842-z
3	Outcomes after robot-assisted pancreaticoduodenectomy for periampullary lesions.	Zeh, Herbert J	Division of Surgical Oncology, Department of Surgery, University of Pittsburgh, Pittsburgh, PA, USA. zehh@upmc.edu	North America	Annals of surgical oncology (2012), vol. 19, no. 3, p. 864-70.	10.1245/s10434-011-2045-0
4	A pancreatic cancer multidisciplinary clinic: insights and outcomes.	Zeh, Herbert J	Division of Surgery, Allegheny General Hospital, Pittsburgh, Pennsylvania. Department of Biostatistics, University of Pittsburgh Cancer Institute, Pittsburgh, Pennsylvania. Cancer Registries, University of Pittsburgh Medical Center, Pittsburgh, Pennsylvania. International Resources, University of Pittsburgh Medical		The Journal of surgical research (2016-05-15), vol. 202, no. 2, p. 246-52.	10.1016/j.jss.2016.01.021

Author	# Publication	Publication trendline	Author/Co-author Region	Overall Official
Saif, Muhammad Wasif	186			
Okusaka, Takuji	108			
Ikeda, Masafumi	70			
Isayama, Hiroyuki	70			
Büchler, Markus W	66			
Furuse, Junji	60			
Kokudo, Norihiro	60			
Hidalgo, Manuel	59			
Nakai, Yousuke	58			
O'Reilly, Eileen Mary	55			
Wolfgang, Christopher L	54			
Herman, Joseph M	53			
Koike, Kazuhiko	52			
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Literature:
Identify Abstract sections and extract keywords

Literature: Abstract sections (Method & Results) extracted with VP-SCE, links to clinical trials

	Source	Clinical Trials	Method	Results
1 Link	World journal of surgery (2017-02), vol. 41, no. 2, p. 386-393.	NCT02512159	MATERIALS AND METHODS: It was a prospective randomized clinical trial conducted over 144 patients with lower limbs ulcers. Patients were randomized into two groups of 72 patients: Experimental group were treated with debridement, cure and a handcrafted vacuum-assisted device that was changed every 72 h. Control group was treated with debridement and cure with soap every 24 h. Ulcers were evaluated every 72 h and on 10th day. The presence of systemic inflammatory response, pain, granulation tissue and viability for discharge was registered and analyzed .	RESULTS: After exclusion of 18 patients, 126 were included, 65.1% were men with an average of 58 years. Sole region ulcer by diabetic foot was the more frequent in both groups (73%). Leukocytes count, systemic inflammatory response and pain were significantly lower in experimental group (p < 0.05). Discharge criteria and granulation tissue were present earlier in experimental group (p < 0.05).
2 Link	Journal of foot and ankle research (2018), vol. 11, p. 22.	NCT02317835	Methods: Plantar skin foot temperatures were measured with the novel thermal imaging device (Diabetic Foot Ulcer Prevention System (DFUPS), constructed by Photometrix Imaging Ltd) and also with a hand-held infrared spot thermometer (Thermofocus® 01500A3, Tecnimed, Italy) after 20 min of barefoot resting with legs supported and extended in 105 subjects (52 males and 53 females; age range 18 to 69 years) as part of a multicentre clinical trial. The temperature differences between the right and left foot at five regions of interest (ROIs), including 1st and 4th toes, 1st, 3rd and 5th metatarsal heads were calculated. The intra-instrument agreement (three repeated measures) and the inter-instrument agreement (hand-held thermometer and thermal imaging device) were quantified using intra-class correlation coefficients (ICCs) and the 95% confidence intervals (CI).	Results: Both devices showed almost perfect agreement in replication by instrument. The intra-instrument ICCs for the thermal imaging device at all five ROIs ranged from 0.95 to 0.97 and the intra-instrument ICCs for the hand-held-thermometer ranged from 0.94 to 0.97. There was substantial to perfect inter-instrument agreement between the hand-held thermometer and the thermal imaging device and the ICCs at all five ROIs ranged between 0.94 and 0.97.
3 Link	Wounds : a compendium of clinical research and practice (2016), vol. 28, no. 3, p. 70-7.	NCT02209051	MATERIALS AND METHODS: This prospective, open-label, randomized, parallel group trial was implemented at 8 clinical sites in the United States. Eligibility criteria included adults with type 1 or type 2 diabetes mellitus who have 1 or more ulcers with a Wagner classification of grade 1 or superficial 2 measuring between 1 cm2 and 25 cm2 in area, presenting for more than 1 month with no signs of infection/osteomyelitis; ABI > 0.7; HbA1c Less than 12%; and serum creatinine less than 3.0 mg/dL. Eligible subjects were randomized (1:1) to receive either SOC alone (n = 14) or DAMA+SOC (n = 15) until wound closure or 6 weeks, whichever occurred first. The endpoint was the proportion of subjects with complete wound closure (defined as complete reepithelialization without drainage or need for dressings). UNLABELLED: Delayed closure of foot ulcers is a primary factor leading to lower extremity amputation in patients with diabetes, creating great demand for products or therapies to accelerate the rate of wound closure in this population. This study (ClinicalTrials.gov Identifier: NCT02209051) was designed to evaluate dehydrated amniotic membrane allograft (DAMA) (AMNIOEXCEL, Derma Sciences Inc, Princeton, NJ) plus standard of care (SOC) compared to SOC alone for the closure of chronic diabetic foot ulcers (DFUs).	RESULTS: Thirty-five percent of subjects in the DAMA+SOC cohort achieved complete wound closure at or before week 6, compared with 0% of the SOC alone cohort (intent-to-treat population, P = 0.017). There was a more robust response noted in the per protocol population, with 45.5% of subjects in the DAMA+SOC cohort achieving complete wound closure, while 0% of SOC-alone subjects achieved complete closure (P = 0.0083). No treatment-related adverse events were reported.
4 Link	Diabetes care (2015), vol. 38, no. 2, p. 302-7.	NCT02123628		RESULTS: Forty patients followed at five French general hospitals were randomized between January 2007 and January 2009, with 20 treated for 6 weeks and 20 treated for 12 weeks with antibiotics. The two groups were comparable for all variables recorded at inclusion in the study. Remission was obtained in 26 (65%) patients, with no significant differences between patients treated for 6 versus 12 weeks (12/20 vs. 14/20, respectively; P = 0.50). We did not identify any significant parameters associated with patient outcome. Fewer patients treated for 6 weeks experienced gastrointestinal adverse events related to antimicrobial therapy compared with patients treated for 12 weeks (respectively, 15 vs. 45%; P = 0.04).
5 Link	Trials (2015-Mar-22), vol. 16, p. 108.	NCT01996995	METHODS/DESIGN: The primary aim is to evaluate the efficacy of four sessions of Nd:YAG 1064 nM laser application on the one-year clinical and microbiological cure rate in a randomized, double-blind, sham-controlled design with blinded outcome assessment. Mandatory inclusion criteria are diagnosis of diabetes, risk factors for developing foot ulcers defined as a modified Simm's classification score 1 or 2 and either neuropathy or PAD. A total of 64 patients are randomized to intervention or sham treatment performed by a podiatrist.	
	Diabetologia (2014), vol. 57, no. 8, p. 1703-10.	NCT01957930	METHODS: We re-determined the skin microcirculation of 72 patients (ICT 35 vs ST 37) from the original Stockholm Diabetes Intervention Study with iontophoresis topically applied with the following vasoactive stimuli: acetylcholine (ACh) (endothelial-dependent vasodilatation),	RESULTS: During the median 28 years of follow-up, three patients developed ischaemic foot ulcers in the ICT group compared with ten in the ST group (logrank,

	Title	Clinical Trials	Source	Results	Results extracted terms
1 Link	**Sucrose octasulfate dressing versus control dressing in patients with neuroischaemic diabetic foot ulcers (Explorer): an international, multicentre, double-blind, randomised, controlled trial.**	NCT01717183	The lancet. Diabetes & endocrinology (2018-03), vol. 6, no. 3, p. 186-196.	FINDINGS: Between March 21, 2013, and March 31, 2016, we randomly assigned 240 individuals to treatment: 126 to the sucrose octasulfate dressing and 114 to the control dressing. After 20 weeks, wound closure occurred in 60 patients (48%) in the sucrose octasulfate dressing group and 34 patients (30%) in the control dressing group (18 percentage points difference, 95% CI 5-30; adjusted odds ratio 2·60, 95% CI 1·43-4·73; p=0·002). In both groups, the most frequent adverse events were infections of the target wound: 33 wound infections in 25 (20%) patients of 126 in the sucrose octasulfate dressing group and 36 in 32 (28%) patients of 114 in the control dressing group. Minor amputations not affecting the wound site were also reported in one (1%) patient in the sucrose octasulfate dressing group and two (2%) patients in the control dressing group. Three (2%) patients assigned to the sucrose octasulfate dressing and four (4%) assigned to the control dressing died, but none of the deaths were related to treatment, procedure, wound progression, or subsequent to amputation.	amputation wound closure
2 Link	**The Effect of Telemedicine Follow-up Care on Diabetes-Related Foot Ulcers: A Cluster-Randomized Controlled Noninferiority Trial.**	NCT01710774	Diabetes care (2018-01), vol. 41, no. 1, p. 96-103.	RESULTS: Using mixed-effects regression analysis, we found that TM was noninferior to SOC regarding healing time (mean difference -0.43 months, 95% CI -1.50, 0.65). When competing risk from death and amputation were taken into account, there was no significant difference in healing time between the groups (subhazard ratio 1.16, 95% CI 0.85, 1.59). The TM group had a significantly lower proportion of amputations (mean difference -8.3%, 95% CI -16.3%, -0.5%), and there were no significant differences in the proportion of deaths, number of consultations, or patient satisfaction between groups, although the direction of the effect estimates for these clinical outcomes favored the TM group.	amputation Healing
3 Link	**Evaluation of the effectiveness and cost-effectiveness of lightweight fibreglass heel casts in the management of ulcers of the heel in diabetes: a randomised controlled trial.**	ISRCTN62524796	Health technology assessment (Winchester, England) (2017-05), vol. 21, no. 34, p. 1-92.	MAIN OUTCOME MEASURES: The primary outcome measure was ulcer healing (confirmed by a blinded observer and maintained for 4 weeks) within 24 weeks. Other outcome measures included the time taken for the ulcer to heal, the percentage reduction in the cross-sectional area, the reduction in local pain, amputation, survival and health economic analysis. The study was powered to define a difference in healing of 15% (55% intervention vs. 40% control). RESULTS: Forty-four per cent (nâ€‰=â€‰94) of the intervention group healed within 24 weeks, compared with 37% (nâ€‰=â€‰80) of the control participants (odds ratio 1.42, 95% confidence interval 0.95 to 2.14; pâ€‰=â€‰0.088), using an intention-to-treat analysis. No differences were observed between the two groups for any secondary outcome.	amputation Healing
4 Link	**An integrated wound-care pathway, supported by telemedicine, and competent wound management-Essential in follow-up care of adults with diabetic foot ulcers.**	NCT01710774	International journal of medical informatics (2016-10), vol. 94, p. 59-66.	RESULTS: Three themes emerged from the interpretive analysis: competence of healthcare professionals, continuity of care, and easy access. This was independed of types of follow-up that had limited impact on the patients' follow-up experiences. Competence of healthcare professionals and continuity of care were crucial, because they can either enhance or jeopardize wound care. If these two latter factors were absent, patients would lose confidence in the wound care process. If this happened, patients pointed out that the expert knowledge of a specialist clinic was essential to receive good care. When telemedicine functioned optimally, telemedicine was an advantage in the treatment, because the images quickly captured changes in the wound healing that immediately could be corrected. Easy access is important for patients, but the importance of accessibility appears to be primary when the other two factors were present.	Healing wound healing

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