Software for
Business Intelligence

BizInt Smart Charts

VP-SCE and BizDash: Examples and Ideas

Summer 2022

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BizInt Smart Charts Resources

- **Mini Guide:** Our “manual” – a booklet with all the key features
- **Webinars**: Short, topical, recordings on the site- Thanks for joining us!
- **Cookbook:** ideas with step by step directions to replicate
- **BizDash:** We use our tools to run analysis and create visualizations.

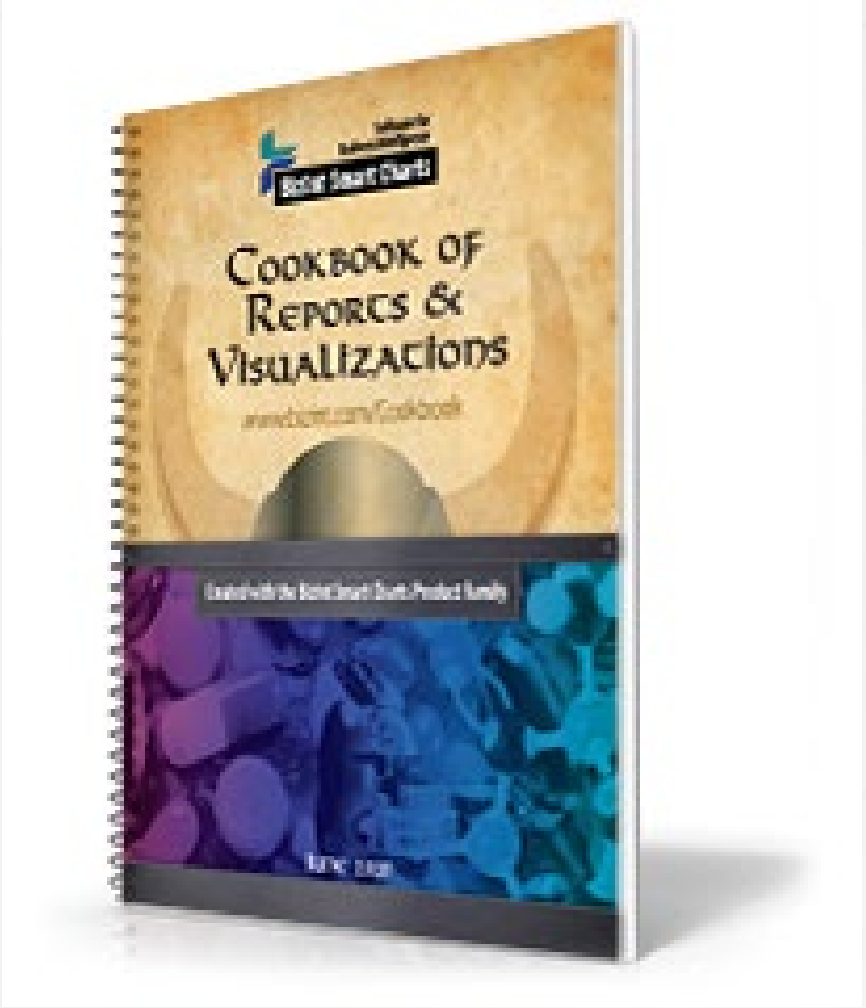
BizInt Smart Strategy Dashboards (BizDash)

BizDash BizInt Smart Strategy Dashboards

- Don’t have the time to learn the BizInt tools?
- BizInt will use the BizInt Smart Charts tools to build BizInt Smart Strategy Dashboards and/or other reports/visualizations for you.
- Could “jumpstart” using the tools yourselves?
- Included in your BizInt license.
- See the Cookbook for ideas: bizint.com/Cookbook

“Cookbook” of samples & techniques

- The **Cookbook** is a collection of sample **reports and visualizations** which you can create with the BizInt Smart Charts product family.
- *New version for v12 now online*
  bizint.com/Cookbook

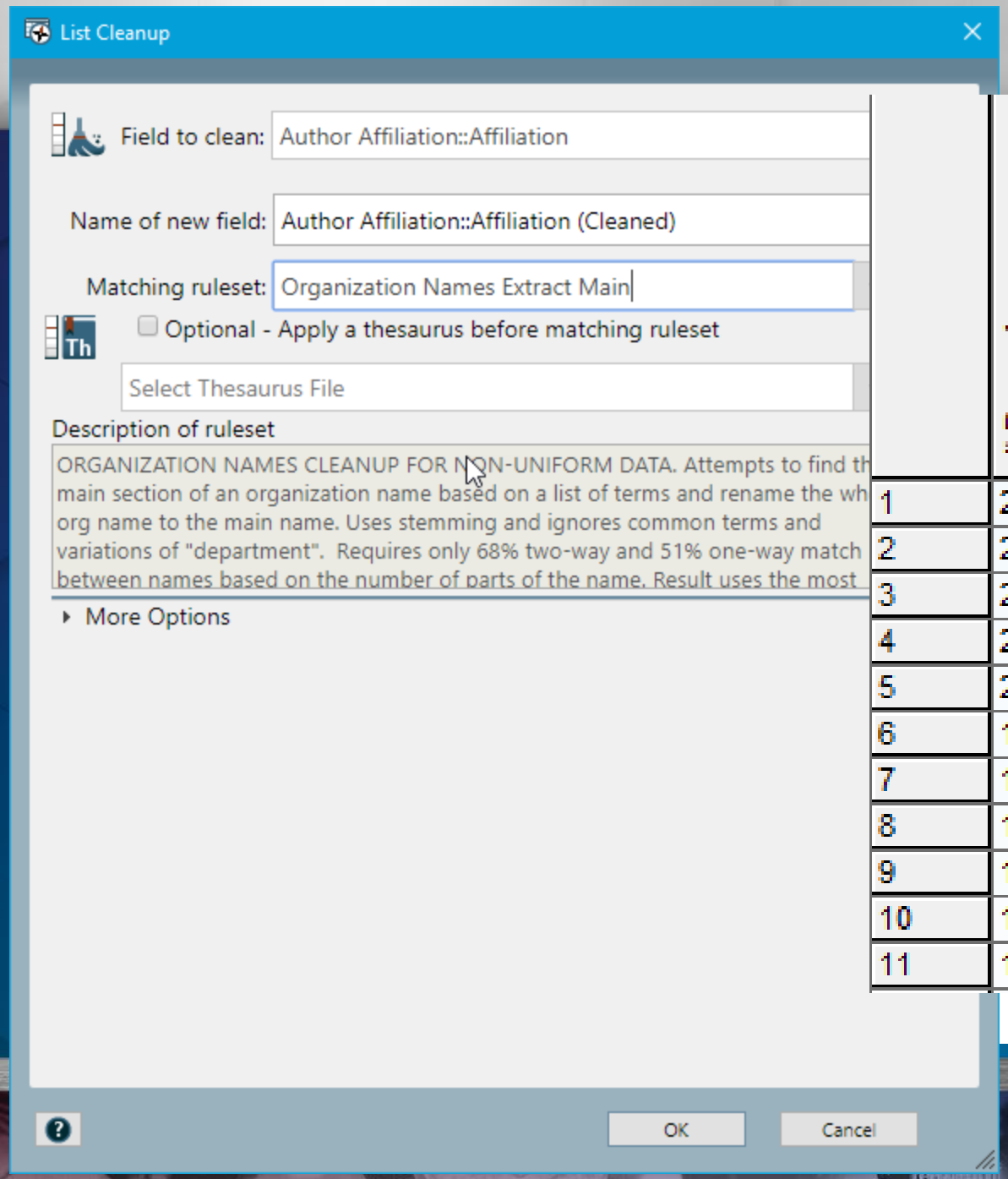


VP-SCE: Commonly Used Features

- **Normalize** Phase and Status
- **List Cleanup** – Company names
- **Thesauri** – Speed Up Clean-up
- **Further Processing –** Remove text from date fields
- **Visualizations** – Piano Chart, Bubble Chart, Timelines, Bullseye
- **Concatenate & Merge** Fields
- **Customize Thesauri** – type of compound

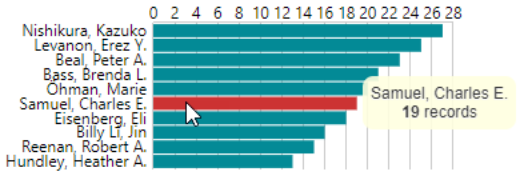
Some Recent BizDash Analyses

Key Opinion Leaders: Author Affiliation analysis



	# Records	# Instances	Author Affiliation	
			Author (Cleaned) (1)	Affiliation (Cleaned)
1	27	27	Nishikura, Kazuko	Wistar Institute
2	25	25	Levanon, Erez Y.	Bar-Ilan University
3	23	23	Beal, Peter A.	University of Californ
4	21	21	Bass, Brenda L.	University of Utah
5	20	20	Öhman, Marie	Stockholm University
6	19	19	Samuel, Charles E.	University of Californ
7	18	18	Eisenberg, Eli	Tel-Aviv University
8	16	16	Billy Li, Jin	Stanford Univ
9	15	15	Reenan, Robert A.	Brown University
10	13	13	Hundley, Heather A.	Indiana University
11	11	11	Chen, Polly Leilei	National University o

ADAR RNA top authors

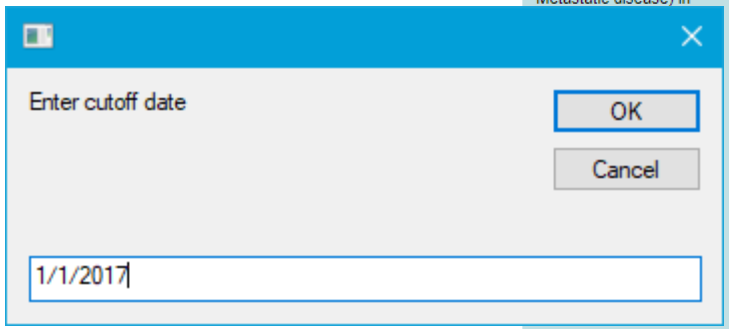


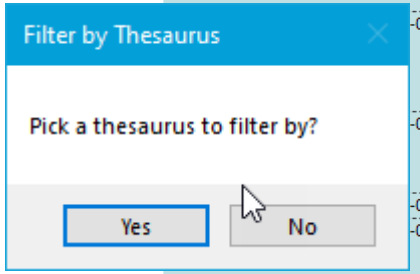
	Title	Author Affiliation		Source	Index Terms	Author Keywords	Abstract
		Author (Cleaned) (1)	Affiliation (Cleaned)				
32.	**ADARs: Viruses and innate immunity**	Samuel, Charles E.	University of California	Current Topics in Microbiology and Immunology (2012), vol. 353, no. 1, p. 163-195.	deamination innate immunity ribosome RNA replication RNA structure virogenesis virus virus genome virus infection article base mispairing base pairing catalysis deamination enzyme substrate gene replication genetic transcription human innate immunity nonhuman nucleotide sequence persistent virus infection priority journal ribosome RNA editing RNA replication RNA stability RNA structure RNA translation virogenesis virus genome		Double-stranded RNA (dsRNA) functions both as a substrate of ADARs and also as a molecular trigger of innate immune responses. ADARs, adenosine deaminases that act on RNA, catalyze the deamination of adenosine (A) to produce inosine (I) in dsRNA. ADARs thereby can destablize RNA structures, because the generated I:U mismatch pairs are less stable than A:U base pairs. Additionally, I is read as G instead of A by ribosomes during translation and by viral RNA-dependent RNA polymerases during RNA replication. Members of several virus families have the capacity to produce dsRNA during viral genome transcription and replication. Sequence changes (A-G, and U-C) characteristic of A-I editing can occur during virus growth and persistence. Foreign viral dsRNA also mediates both the induction and the action of interferons. In this chapter our current understanding of the role and significance of ADARs in the context of innate immunity, and as determinants of the outcome of viral infection, will be considered. © 2011 Springer-Verlag Berlin Heidelberg.
48.	**Double-stranded RNA adenosine deaminase (ADAR) as a modulator of antiviral innate immunity**	George, Cyril X. Li, Zhiqun Okonski, Kristina M. Pfaller, Christian K. Samuel, Charles E.	University of California University of California University of California University of California University of California	Cytokine (Oct 2011), vol. 56, no. 1, p. 9. Meeting info: 9th Joint Meeting of International Cytokine Society and International Society for Interferon and Cytokine Research - Cytokines and	society innate immunity mouse interferon induction DNA virus promoter region phosphorylation mutant Polyoma virus gene expression hydrogen bond deamination		Adenosine deaminase acting on RNA (ADAR1) catalyzes the C-6 deamination of adenosine (A) to generate inosine (I) in double-stranded (ds) RNAs. Because I hydrogen bonds as G with C, instead of A with U, A-to-I editing can lead to genetic recoding of mRNAs and destabilization of dsRNA structures. Protein kinase PKR is activated by dsRNA and inhibits translation by phosphorylation of initiation factor eIF-2. Both ADAR1 and PKR are interferon inducible dsRNA-binding proteins. While Pkr gene expression occurs from a single inducible promoter, Adar1 expression is from multiple promoters, one of which is IFN inducible that encodes an N-terminally extended p150

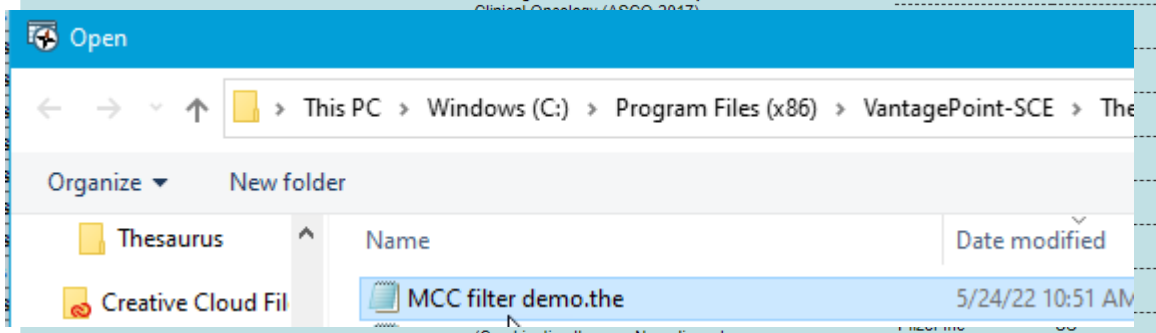
VP-SCE Analysis to speed up review:
Filter key columns by date and keyword list

4.

Database	Common Drug Name	Row Status	Drug Name	Latest Change
4a CORTL | link	avelumab	Updated	avelumab	Phase-I/II clinical trials in Solid tumours (Combination therapy, Late-stage disease, Metastatic disease) in
4b Adis | link				
4c PipeIn | link				







Drug Development History (Extended)

Event Date	Update Type	Event	Update Date
2017-08-02	Phase Change - I/II	Phase-I/II clinical trials in Solid tumours (Combination therapy, Late-stage disease, Metastatic disease) in USA (IV) (NCT03217747)	2017-09-08
2017-07-21	Regulatory Status	Merck expects a decision on approval for Merkel cell carcinoma (Metastatic disease, Second-line therapy or greater, Monotherapy, In adults) in European Union in the third quarter of 2017	2017-08-08
2017-07-20	Phase Change - II	Phase-II clinical trials in Merkel cell carcinoma (Metastatic disease, First-line therapy) (IV) (NCT02155647)	2017-07-25
2017-07-20	Regulatory Status	Committee for Medicinal Products for Human Use (CHMP) of EMA adopts a positive opinion recommending approval of avelumab for Merkel cell carcinoma (Second-line therapy or greater, Metastatic disease, Monotherapy, In adults)	2017-07-25
2017-07-17	Phase Change - II	Phase-II clinical trials in Colorectal cancer (Combination therapy, Metastatic disease, First-line therapy) in Germany (IV) (NCT03174405)	2017-08-14
-06-20	Trial Update	eFFECTOR Therapeutics plans a phase II trial for Colorectal cancer (Second-line therapy or greater, Combination therapy) in the third quarter of 2017 (IV) (NCT03258398)	2017-09-08
-06-20	Licensing Status	eFFECTOR Therapeutics, Pfizer and Merck agree to co-develop eFT 508 in combination with avelumab for Colorectal cancer	2017-07-03
-06-16	Financial Update	Credit Suisse financial data update	2017-09-10
-06-04	Scientific Update	Updated efficacy data from the phase I JAVELIN Solid Tumour trial in Solid tumour presented at the 53rd Annual Meeting of the American Society of	2017-07-20
		(Combination therapy, Neoadjuvant therapy)	
2017-05-09	Licensing Status	VAXIMM, Merck and Pfizer agree to co-develop VXM 01, in combination with Avelumab, for Glioblastoma and Colorectal cancer	2017-05-22
2017-05-09	Phase Change -	Preclinical trials in Colorectal cancer	2017-05-22

Development Status (Current)

Company	Country	Status	Indication	Date
Merck Serono SA	US	Launched	Metastatic bladder cancer	2017-05-09
Pfizer Inc	US	Launched	Metastatic bladder cancer	2017-05-09
Pfizer Inc	US	Launched	Merkel cell carcinoma	2017-03-23
Merck Serono SA	US	Launched	Merkel cell carcinoma	2017-03-23
Pfizer Inc	Japan	Pre-registration	Merkel cell carcinoma	2017-03-07
Merck Serono SA	Japan	Pre-registration	Merkel cell carcinoma	2017-03-07
Pfizer Inc	Europe	Pre-registration	Merkel cell carcinoma	2016-10-31
Merck KGaA	Europe	Pre-registration	Merkel cell carcinoma	2016-10-31
Pfizer Inc	Far East	Phase 3 Clinical	Metastatic head and neck cancer	2016-11-30
Pfizer Inc	Japan	Phase 3 Clinical	Metastatic bladder cancer	2015-12-22
Pfizer Inc	Europe	Phase 3 Clinical	Metastatic ovary cancer	2016-05-31
Merck KGaA	Europe	Phase 3 Clinical	Metastatic ovary cancer	2016-05-31
Pfizer Inc	US	Phase 3 Clinical	Metastatic ovary cancer	2016-05-31
Merck KGaA	US	Phase 3 Clinical	Metastatic ovary cancer	2016-05-31
Pfizer Inc	Japan	Phase 3 Clinical	Metastatic ovary cancer	2016-05-31
Pfizer Inc	Far East	Phase 3 Clinical	Metastatic ovary cancer	2016-05-31
Merck KGaA	Far East	Phase 3 Clinical	Metastatic ovary cancer	2016-05-31
Pfizer Inc	South Korea	Phase 3 Clinical	Head and neck tumor	2017-06-29
Merck KGaA	US	Phase 3 Clinical	Metastatic head and neck cancer	2016-11-30
Pfizer Inc	US	Phase 3 Clinical	Metastatic head and neck cancer	2016-11-30
		Phase 3 Clinical	Metastatic head and neck cancer	2016-11-30
		Phase 3 Clinical	Metastatic head and neck cancer	2016-11-30
		Phase 3 Clinical	Diffuse large B-cell lymphoma	2016-12-16
		Phase 3 Clinical	Diffuse large B-cell lymphoma	2016-12-16
		Phase 3 Clinical	Metastatic bladder cancer	2015-12-22
		Phase 3 Clinical	Metastatic bladder cancer	2015-12-22
		Phase 3 Clinical	Metastatic bladder cancer	2015-12-22
		Phase 3 Clinical	Ovary tumor	2015-12-22
Merck KGaA	US	Phase 3 Clinical	Ovary tumor	2015-12-22
Pfizer Inc	New Zealand	Phase 3 Clinical	Metastatic non small cell lung cancer	2015-10-31
Merck Serono SA	New Zealand	Phase 3 Clinical	Metastatic non small cell lung cancer	2015-10-31
Pfizer Inc	Canada	Phase 3 Clinical	Metastatic non small	2015-10-31

Update Histo

Date	D
2017-08-02	Phase-I/II clinical tumours (Combin stage disease, M in USA (IV) (NCT
2017-07-21	Merck expects a approval for Merk (Metastatic disea therapy or greate adults) in Europe third quarter of 20
2017-07-20	Phase-II clinical t carcinoma (Meta line therapy) (IV)
2017-07-20	Committee for Me for Human Use (adopts a positive recommending ap avelumab for Mer (Second-line ther Metastatic diseas adults)
2017-07-17	Phase-II clinical t cancer (Combina Metastatic diseas therapy) in Germa (NCT03174405)
2017-06-20	eFFECTOR Ther phase II trial for C (Second-line ther Combination ther quarter of 2017 (I
2017-06-20	eFFECTOR Ther and Merck agree 508 in combinatic for Colorectal can
2017-06-16	Credit Suisse fina
2017-06-04	Updated efficacy phase I JAVELIN in Solid tumour p 53rd Annual Mee American Society Oncology (ASCO
2017-06-02	Updated efficacy events data from Renal cell carcinc the 53rd Annual M American Society Oncology (ASCO
2017-05-23	Pfizer and Hoosie Network initiates Renal cell carcinc therapy, Metastat (NCT03035630)
2017-05-10	EpiThany, Merck co-develop EP 1(with avelumab, fo
2017-05-10	EpiThany, Merck phase II trial for E (Combination the therapy)

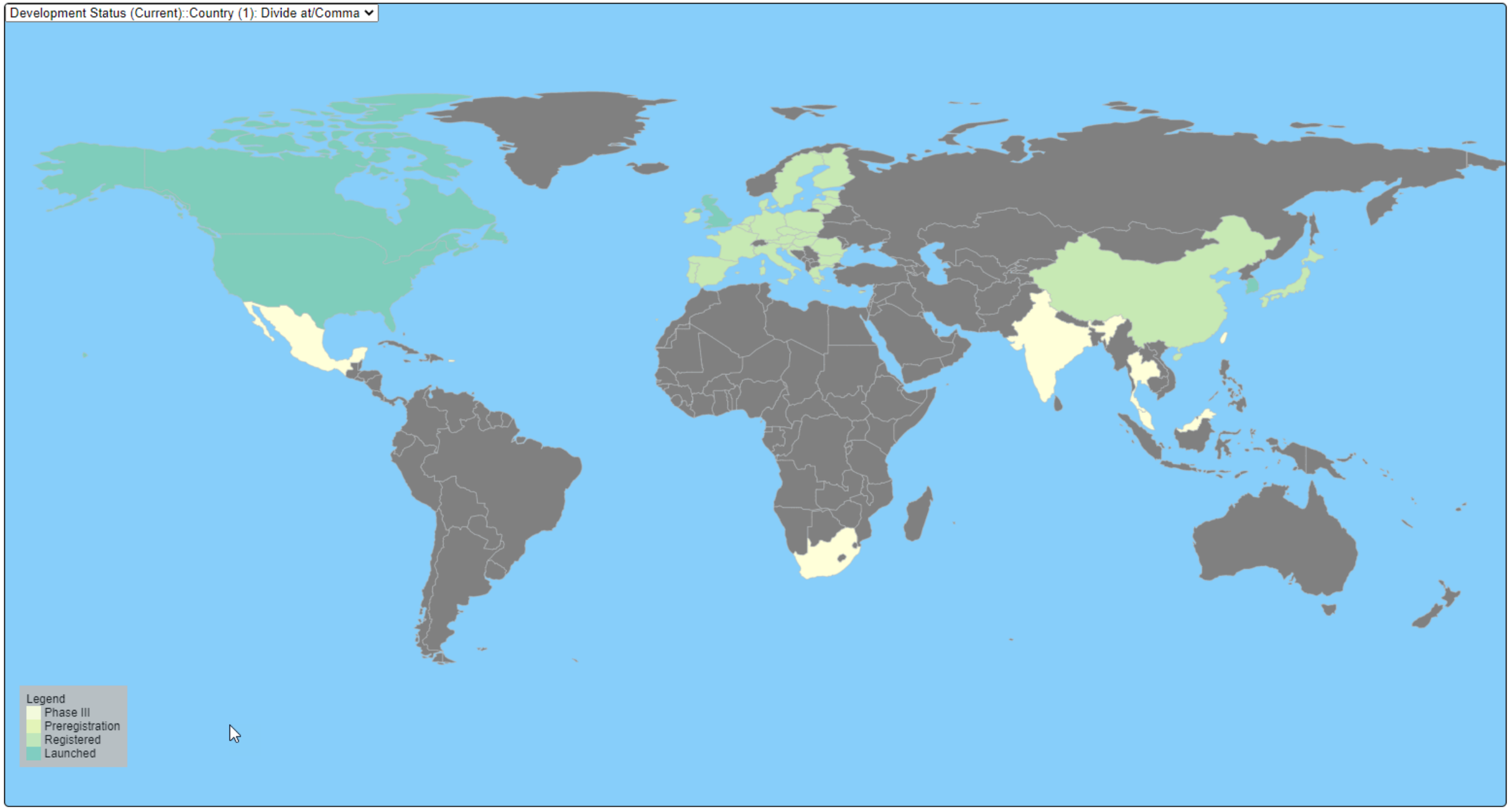
	Database	Common Drug Name	Row Status	Drug Name	Latest Change	COR Dev Status (Current):MCC:Date Range					RDI Drug Dev History (Ext.):MCC:Date Range				Update History:MCC:Date Range	
						Company	Country	Status	Indication	Date	Event Date	Update Type	Event	Update Date	Date	Detail
4.	4a CORTL | link 4b Adis | link 4c PipeIn | link	avelumab	Updated	**avelumab**	Phase-I/II clinical trials in Solid tumours (Combination therapy, Late-stage disease, Metastatic disease) in USA (IV) (NCT03217747)	Merck Serono SA	Japan	Pre-registration	Merkel cell carcinoma	2017-03-07	2017-03-23	Phase Change - Registered	Registered for Merkel cell carcinoma through accelerated procedure (Metastatic disease, Second-line therapy or greater, In adults and In adolescents) in USA (IV) - First global approval	2017-03-27	2017-03-23	Registered for Merkel cell carcinoma through accelerated procedure (Metastatic disease, Second-line therapy or greater, In adults and In adolescents) in USA (IV) - First global approval
						Merck Serono SA	US	Launched	Merkel cell carcinoma	2017-03-23	2017-03-24	Phase Change - Marketed	Launched for Merkel cell carcinoma (Metastatic disease, Second-line therapy or greater, In adults, In adolescents) in USA (IV) - First global launch	2017-03-27	2017-03-24	Launched for Merkel cell carcinoma (Metastatic disease, Second-line therapy or greater, In adults, In adolescents) in USA (IV) - First global launch
						Pfizer Inc	Japan	Pre-registration	Merkel cell carcinoma	2017-03-07	2017-03-31	Trial Update	Merck initiates an expanded access to avelumab for Merkel cell carcinoma (Metastatic disease, Second-line therapy) in France (NCT03089658)	2017-03-31	2017-03-31	Merck initiates an expanded access to avelumab for Merkel cell carcinoma (Metastatic disease, Second-line therapy) in France (NCT03089658)
						Pfizer Inc	US	Launched	Merkel cell carcinoma	2017-03-23	2017-07-20	Phase Change - II	Phase-II clinical trials in Merkel cell carcinoma (Metastatic disease, First-line therapy) (IV) (NCT02155647)	2017-07-25	2017-07-20	Committee for Medicinal Products for Human Use (CHMP) of EMA adopts a positive opinion recommending approval of avelumab for Merkel cell carcinoma (Second-line therapy or greater, Metastatic disease, Monotherapy, In adults)
											2017-07-20	Regulatory Status	Committee for Medicinal Products for Human Use (CHMP) of EMA adopts a positive opinion recommending approval of avelumab for Merkel cell carcinoma (Second-line therapy or greater, Metastatic disease, Monotherapy, In	2017-07-25	2017-07-20	Phase-II clinical trials in Merkel cell carcinoma (Metastatic disease, First-line therapy) (IV) (NCT02155647)
															2017-07-21	Merck expects a decision on approval for Merkel cell carcinoma (Metastatic disease, Second-line therapy or greater, Monotherapy, In adults) in European Union in the third quarter of 2017

VP-SCE Analysis to speed up review: Extract relevant Inclusion criteria

Trial Title	Common Trial ID	Database	Inclusion Criteria	Primary Drugs	Trial Phase	Inclusion Criteria - MCC
QUILT-3.055: A Phase IIb, Single-Arm, Multicohort, Open-Label Study of ALT-803 in Combination With PD-1/PD-L1 Checkpoint Inhibitor in Patients Who Have Disease Progression Following an Initial Response to Treatment With PD-1/PD-L1 Checkpoint Inhibitor Therapy	NCT03228667	56 TT | *link*	Voluntary written informed consent and HIPAA authorization and agree to comply with all protocol-specified procedures and follow-up evaluations Cohort 1 will enroll patients who have disease progression per RECIST v1.1 on or after single-agent checkpoint inhibitor therapy after experiencing an initial response (ie, confirmed CR or PR by RECIST V1.1) while taking checkpoint inhibitor therapy. Patients will be enrolled into distinct cohorts (1a-1k) based on cancer type. Patients must have been treated with checkpoint inhibitor therapy after progressing on SoC therapy for their disease, as per FDA indication detailed below: 1a - For metastatic squamous or nonsquamous NSCLC with progression on or after nivolumab, pembrolizumab, or atezolizumab, initial SoC therapy must have been for disease with progression on or after one prior platinum doublet-based chemotherapy regimen. Patients with EGFR or ALK genomic tumor aberrations should have had disease progression on FDA-approved targeted therapy for these aberrations prior to receiving checkpoint inhibitor. 1b - For metastatic SCLC with disease progression on or after nivolumab monotherapy, initial SoC treatment must have been for disease with progression after platinum-based chemotherapy and at least one other line of therapy prior to receiving checkpoint. 1c - Locally advanced or metastatic urothelial carcinoma as follows: For patients with progression on or after nivolumab monotherapy, initial SoC must have been for disease with progression on or after platinum-based chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-based chemotherapy.	ALT-803 (SC)	II	1e - For histologically confirmed metastatic MCC with progression on or after avelumab or pembrolizumab, initial SoC therapy must have been for disease with progression on or after chemotherapy administered for distant metastatic disease; OR recurrent locally advanced or metastatic MCC not treated with prior systemic therapy for advanced disease.

Customized existing visualizations:
Single drug World Map – phase per country

Paxlovid country status



Customized existing visualizations:
Piano for selected drugs and multiple indications

Launched Sjogren's Drugs – Other Indications

Phase I	Phase I/II	Phase II	Phase II/III	Phase III
rituximab *Biogen Idec* Cancer	**rituximab** *Biogen Idec* Renal transplant rejection	**rituximab** *Biogen Idec* Cancer, Chronic inflammatory demyelinating polyradiculoneuropathy, Glomerulonephritis	**rituximab** *Biogen Idec* Neuromyelitis optica	**rituximab** *Biogen Idec* Anti neutrophil cytoplasmic antibody associated vasculitis, Cancer, Transplant rejection
belimumab *Cambridge Antibody Technology, HGS* Graft versus host disease		**belimumab** *Cambridge Antibody Technology, HGS* Emphysema, Membranous glomerulonephritis, Myasthenia gravis, Renal transplant rejection, Sjogren's syndrome, Systemic scleroderma	**belimumab** *Cambridge Antibody Technology,* HGS Myositis	**belimumab** *Cambridge Antibody Technology, HGS* Anti neutrophil cytoplasmic antibody associated vasculitis, Lupus nephritis
		interferon-alpha, Amarillo *Hayashibara* Influenza virus infections		**abatacept** *Bristol-Myers Squibb* Lupus nephritis, Myositis, Polymyalgia rheumatica, Sjogren's syndrome
		abatacept *Bristol-Myers Squibb* Alopecia areata, Common variable immunodeficiency, Diffuse scleroderma, Graft versus host disease, Interstitial lung diseases, Nephrotic syndrome, Pulmonary sarcoidosis		

Mechanism of Action

- Antibody dependent cell cytotoxicity
- B cell
- IL-2
- Interferon alpha stimulants
- Muscarinic receptor agonists
- Purinoceptor P2U agonists
- T cell
- Thromboxane

VP-SCE Piano Chart

“Consensus”: Selecting only drugs found in multiple databases

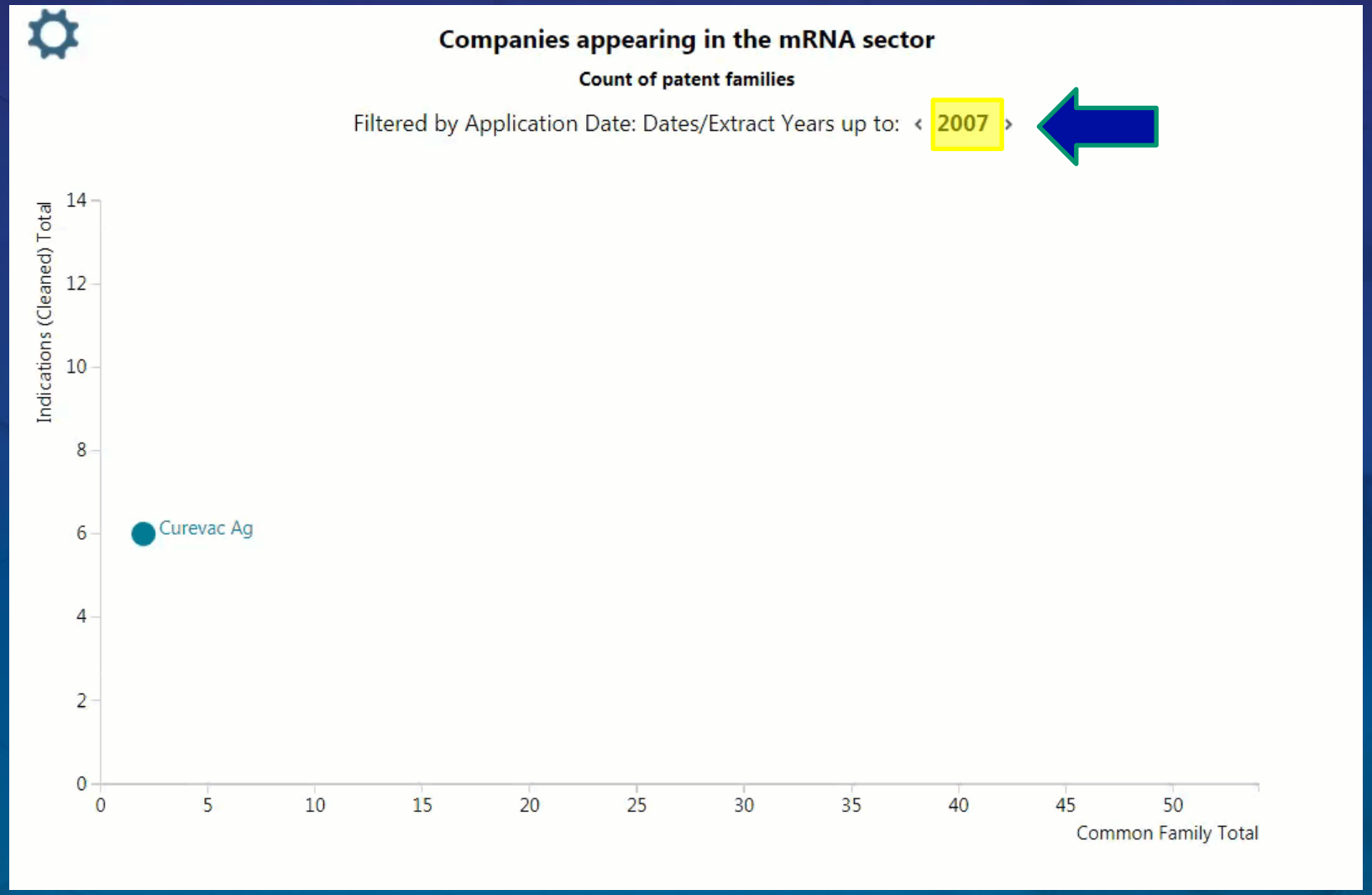
	Primary Drug Name	Common Drug Name	Common Drug Name (record count)	Database	Key Company	Highest Phase (MCC)
1.	avelumab	avelumab	2	1a Phar | link 1b Cort | link	Merck KGaA	Launched
2.	F16-IL2	F16-IL2	2	2a Phar | link 2b Cort | link	Philogen	Phase 2
3.	CST-101	CST-101	2	3a Phar | link 3b Cort | link	NantKwest	Phase 2
4.	tavokinogene telsaplasmid	IT-pIL12-EP	2	4a Phar | link 4b Cort | link	OncoSec Medical	Phase 2
5.	pasireotide	Signifor	2	5a Phar | link 5b Cort | link	Novartis	Phase 1
6.	ID-G100	ID-G100	2	6a Phar | link 6b Cort | link	Immune Design	Phase 1
7.	LTvax	LTvax	2	7a Phar | link 7b Cort | link	APCure	Preclinical
8.	pembrolizumab	pembrolizumab	2	8a Phar | link 8b Cort | link	Merck & Co.	Preclinical
9.	lorvotuzumab mertansine	lorvotuzumab mertansine	2	9a Phar | link 9b Cort | link	ImmunoGen	Discontinued

Compare Columns: What’s the Key Company

	Drug Name	Common Drug Name	Database	Companies	Companies (Key)	Highest Phase (Normalized)	Update Date
1.	Emedastine 1 RDI	Emedastine	1 RDI | link	Nippon Organon (Originator) Alcon (Market Licensee) Alcon Cusi (Market Licensee) Astellas Pharma (Market Licensee) Kolon Pharmaceuticals (Market Licensee) Kowa (Market Licensee) Saluc Pharma (Market Licensee) 1 RDI	Alcon; Nippon Organon 1 RDI	Launched	2019-04-15 1 RDI
2.	Epiceram 2 Phar	Epiceram	2 Phar | link	Ceragenix Promius Pharma BioPro Pharmaceutical 2 Phar	Ceragenix 2 Phar	Launched	2011-05-10 2 Phar
3.	N-palmitoylethanolamide, Stief 3 Phar	N-palmitoylethanolamide, Stief	3 Phar | link	GlaxoSmithKline 3 Phar	GlaxoSmithKline 3 Phar	Launched	2009-07-23 3 Phar
4.	hydrocortisone-17-butyrate 4 Phar	hydrocortisone-17-butyrate	4 Phar | link	Astellas Pharma 4 Phar	Astellas 4 Phar	Launched	2005-03-31 4 Phar
5.	Ruxolitinib - Incyte Corporation/Novartis 5a RDI	ruxolitinib	5a RDI | link 5b Cort | link 5c Phar | link	Incyte Corporation (Originator) Novartis (Licensee) 5a RDI	Incyte 5b Cort	Launched	2020-12-02 5a RDI
6.	Risankizumab - AbbVie/Boehringer Ingelheim 6a RDI	risankizumab	6a RDI | link 6b Cort | link 6c Phar | link	Boehringer Ingelheim (Originator) AbbVie (Licensee) 6a RDI	AbbVie; Boehringer Ingelheim 6a RDI	Launched	2020-10-15 6a RDI
7.	alitretinoin, Basilea 7 Phar	alitretinoin, Basilea	7 Phar | link	Basilea Pharmaceutica Almirall Actelion GlaxoSmithKline 7 Phar	Basilea Pharmaceutica 7 Phar	Launched	2020-08-18 7 Phar

New Visualizations in VP-SCE v12

Developer: Remove/Company Suffix (Cleaned) vs. Highest Phase (Normalized)


Companies appearing in the mRNA sector
Count of patent families
Filtered by Application Date: Dates/Extract Years up to: 2007
Indications (Cleaned) Total
14
12
10
8
6
4
2
0
Curevac Ag
0
5
10
15
20
25
30
35
40
45
50
Common Family Total

Pre-2020 & 2020

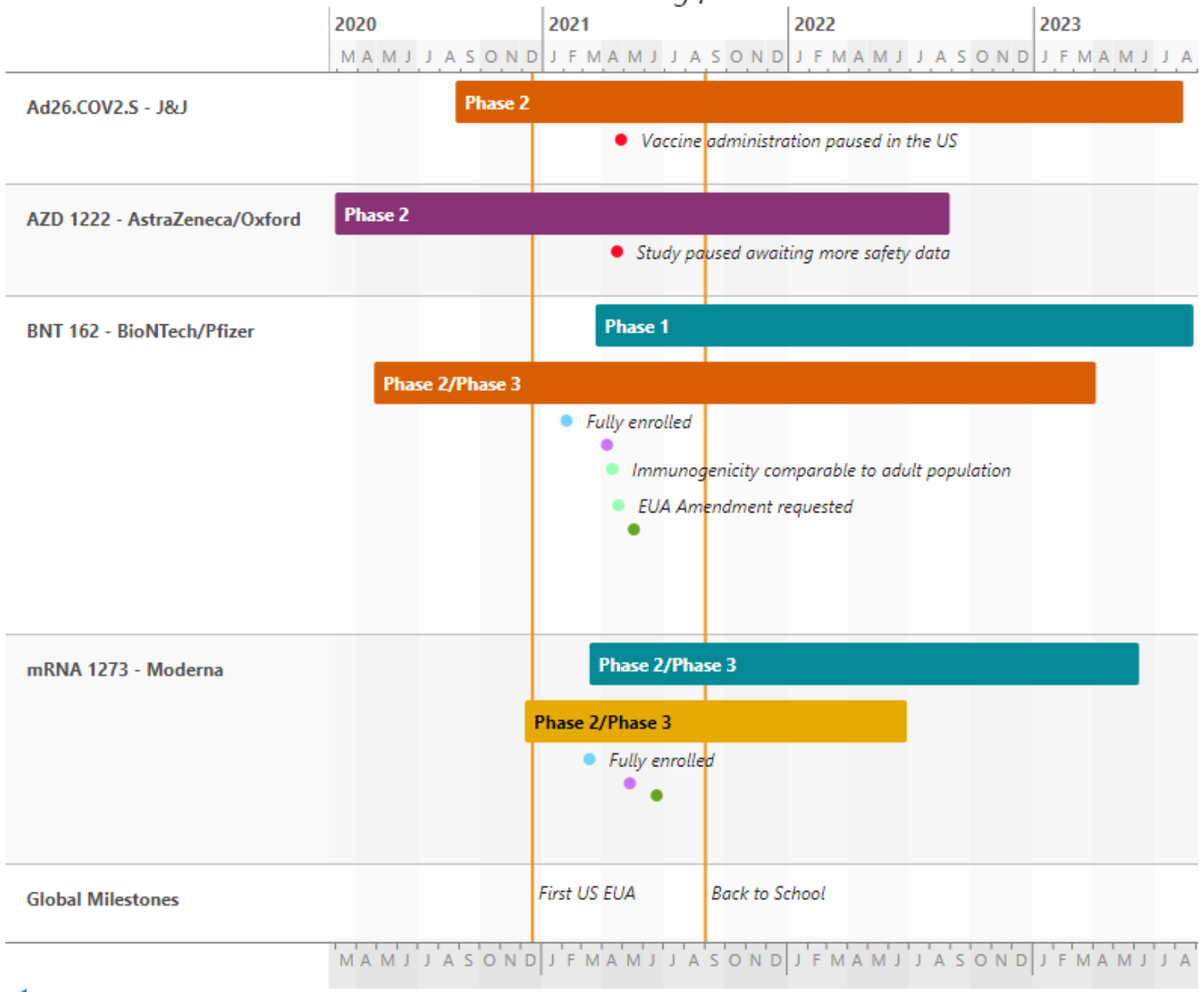
Total	Original Assignee: Remove/Company Suffix (Cleaned)	Pre-2020 AKA, The Before Times	2020 The New Normal
54	Curevac Ag		
41	ModeRNA		
25	BioNTech		
23	Novartis Ag		
10	Glaxosmithkline Bi...		
4	Institut Pasteur		
3	Acuitas		
3	Coley		
3	Etherna Immunoth...		
3	Isis Innovation		

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

COVID-19 Vaccine trials - children and teens

Trial timing for selected vaccines

VP-SCE Timeline℠



Software for Business Intelligence

BizInt Smart Charts

Updated June 15, 2021

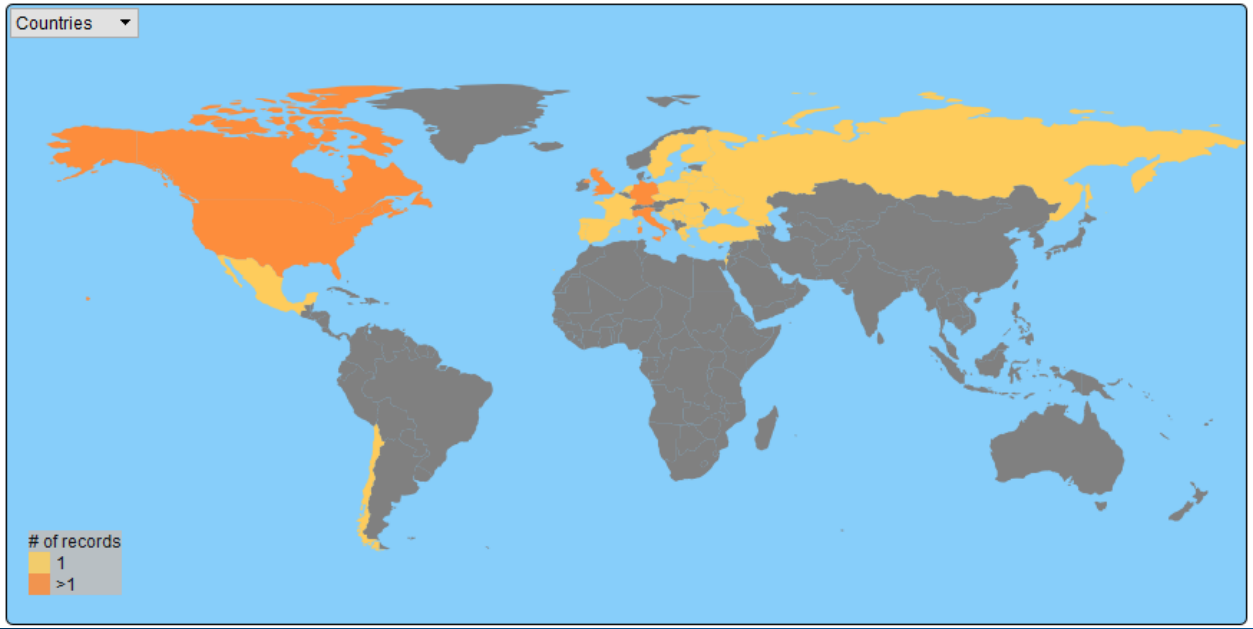
Clinical trials:
Extract primary endpoint terms from trial registries

Chart with endpoint terms extracted and normalized with VP-SCE

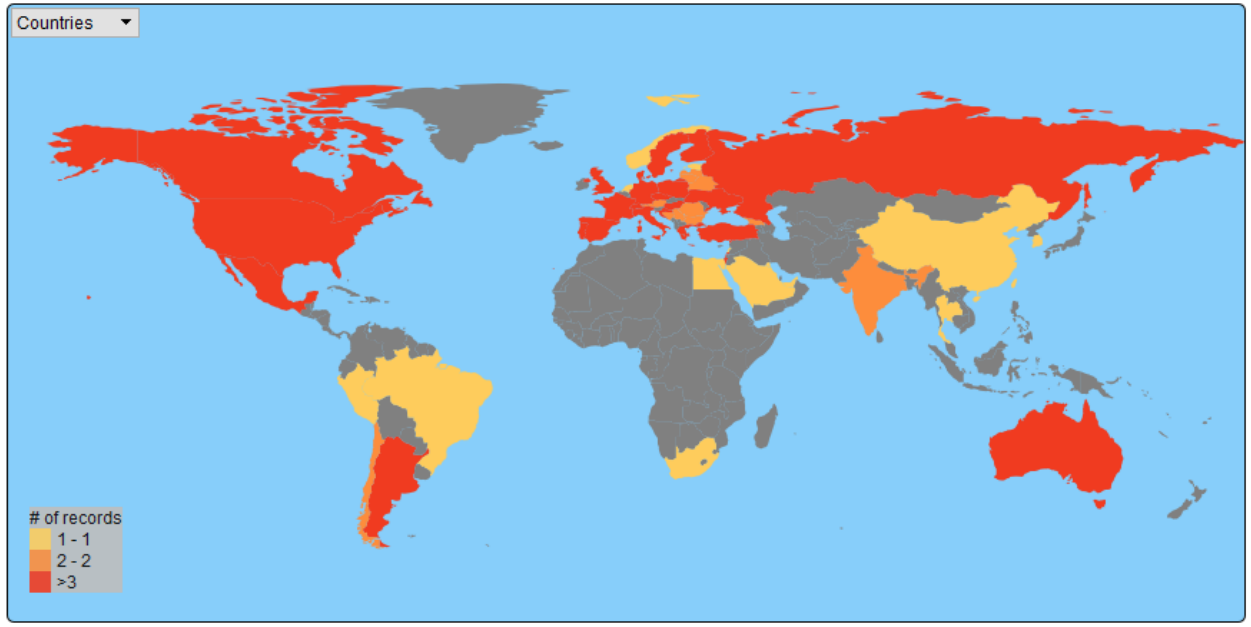
	Trial Title	Database	Common Trial ID	Primary Outcome	Primary Outcome : extracted endpoints	Phase	Sponsor(s)
1.	A Randomized, Double-Blind, Placebo-Controlled, Parallel Group Design Study to Evaluate the Efficacy and Safety of Teriflunomide in Reducing the Frequency of Relapses and Delaying the Accumulation 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?

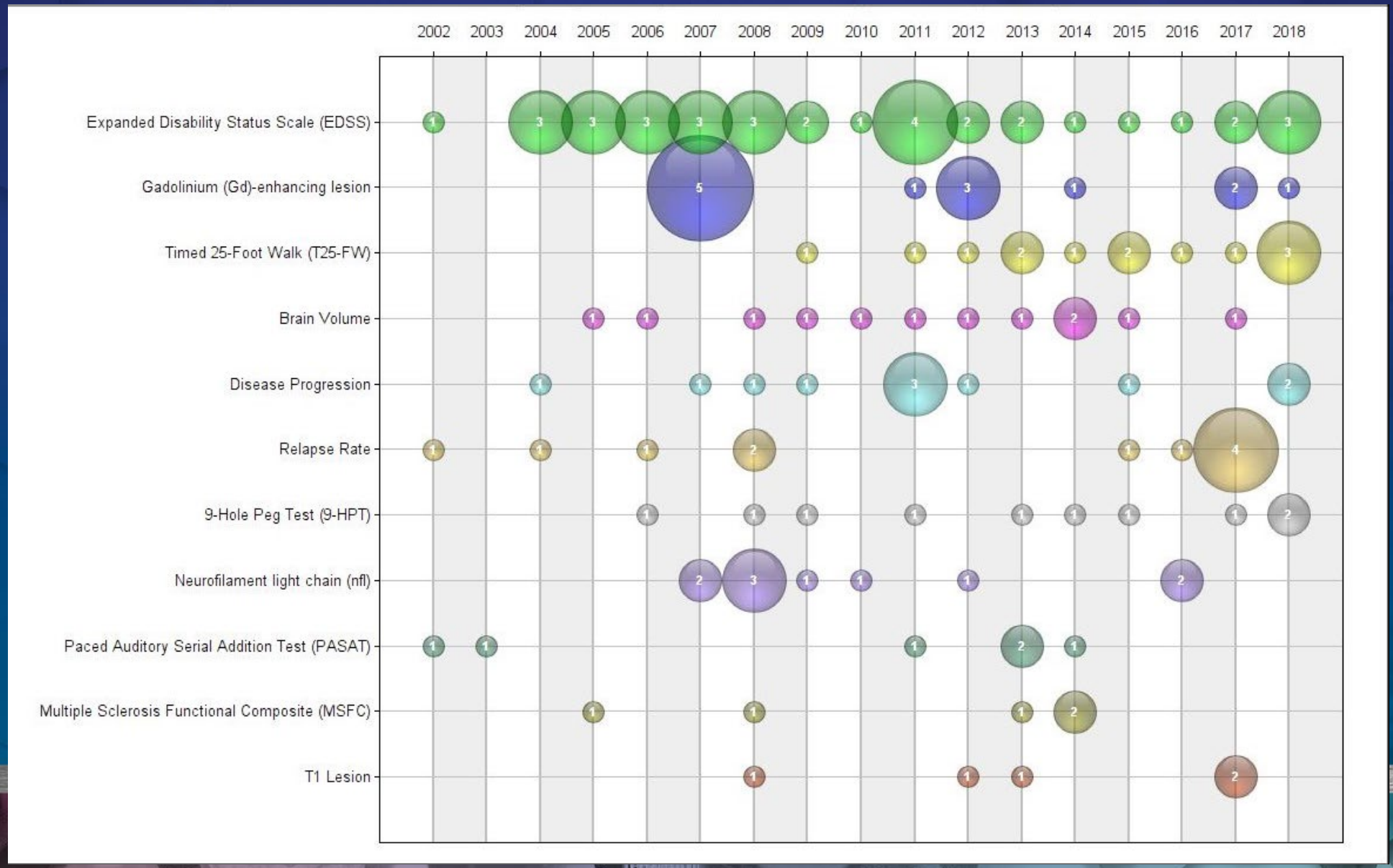
Progressive MS Trials with brain volume/atrophy endpoints (US+EU registries)



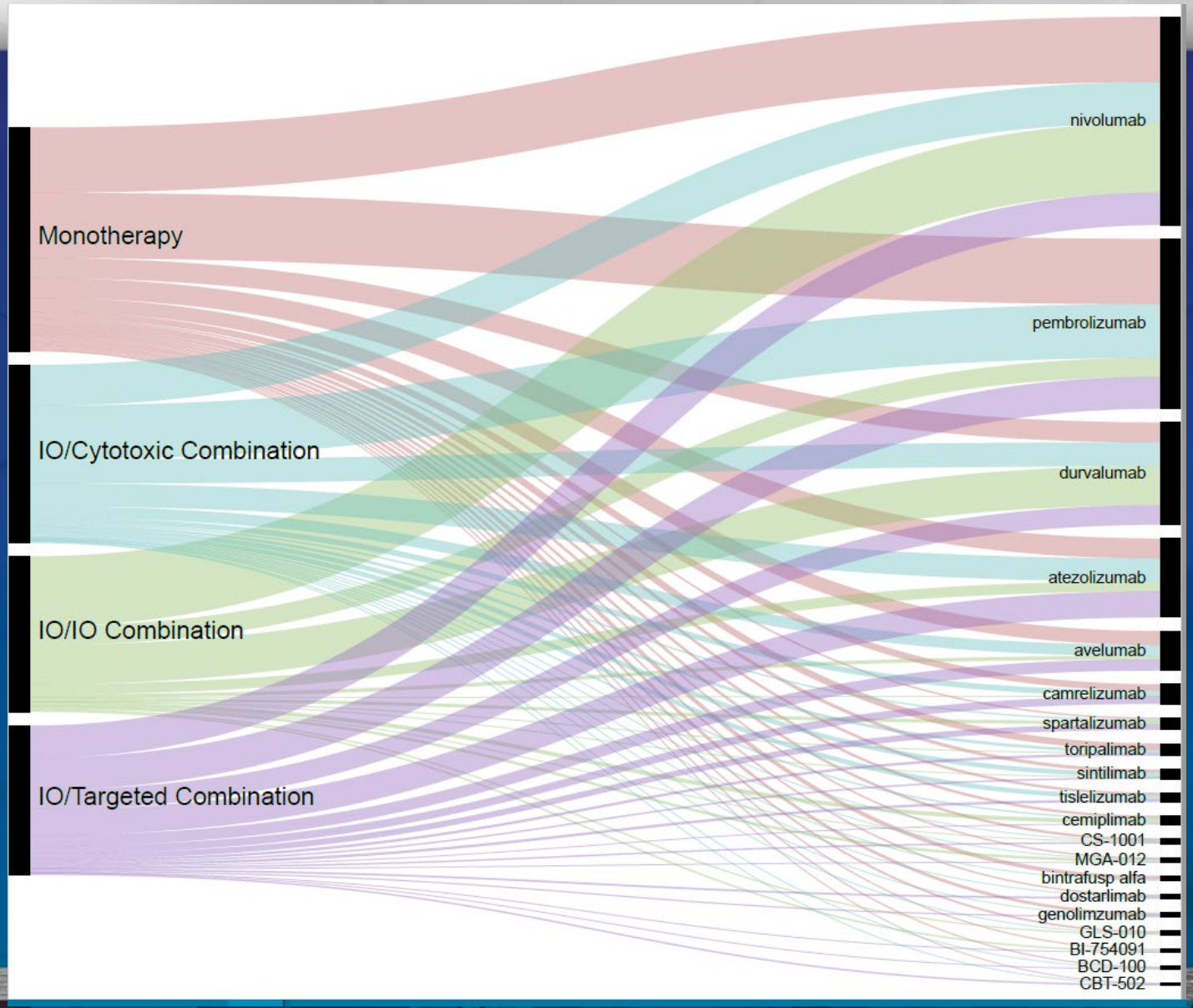
Progressive MS Trials with relapse rate endpoints (US+EU registries)



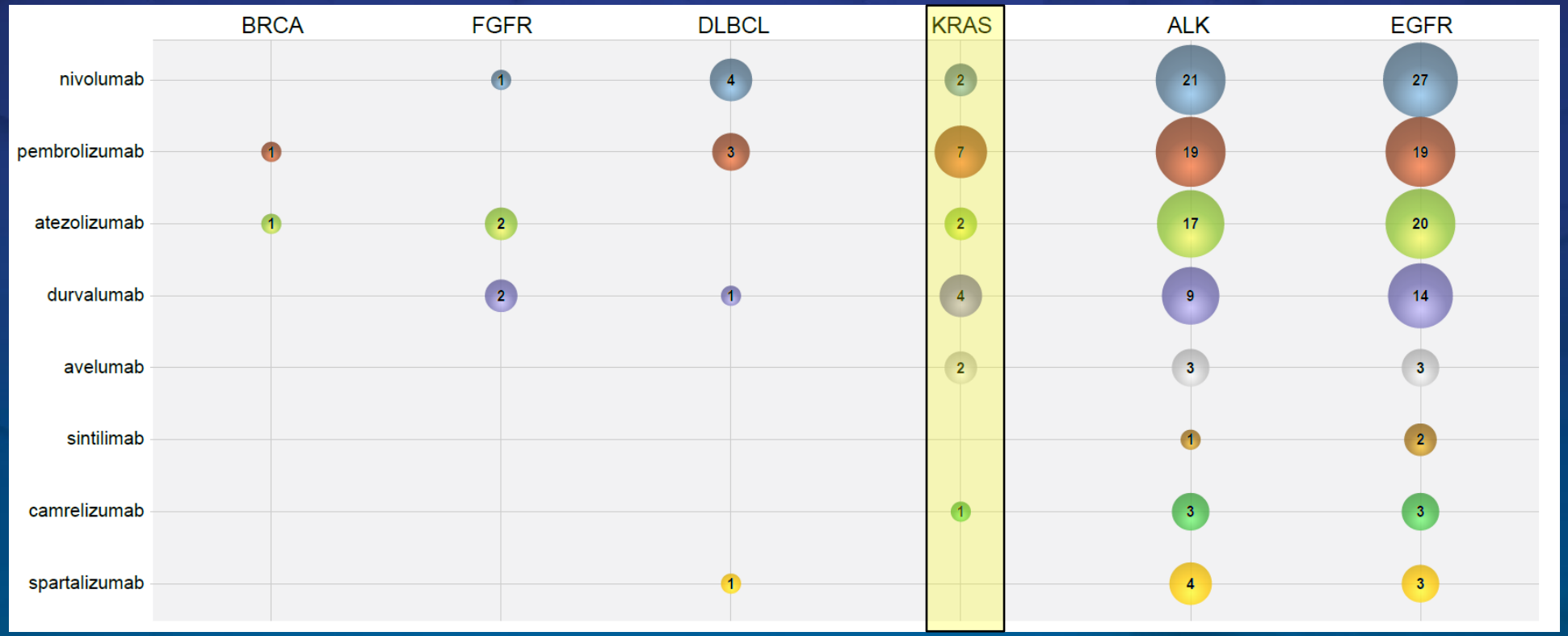
How Do Endpoints Evolve Over Time? Primary Endpoints by Trial Start Year



Clinical trials:
Combination drugs - Identify new partners

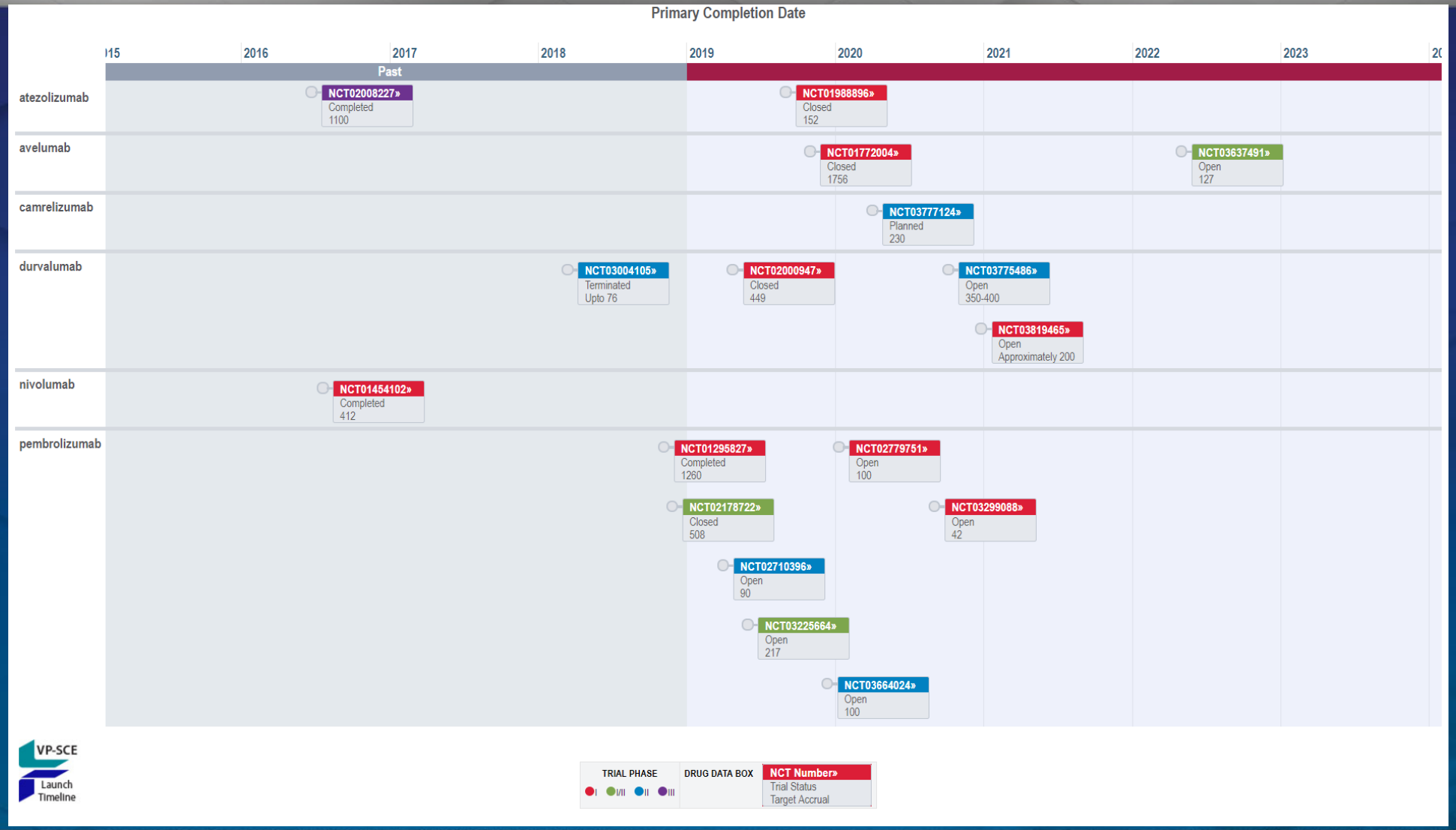


Clinical trials:
Identify new biomarkers for competitive differentation



Review the trials for a single biomarker to assess competitor strategy

Trials for a single biomarker to assess competitor strategy



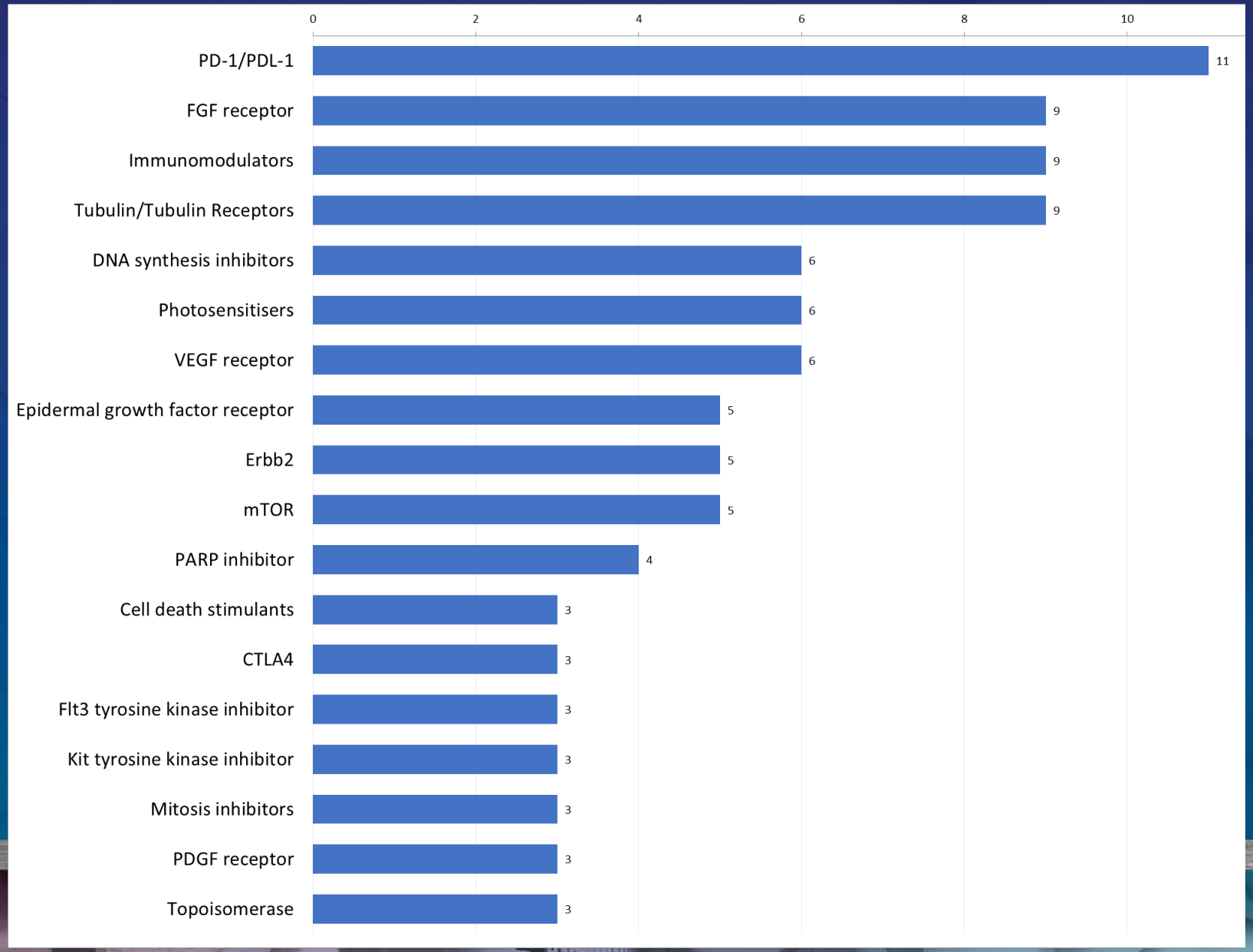
Trials for a single biomarker to assess competitor strategy

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

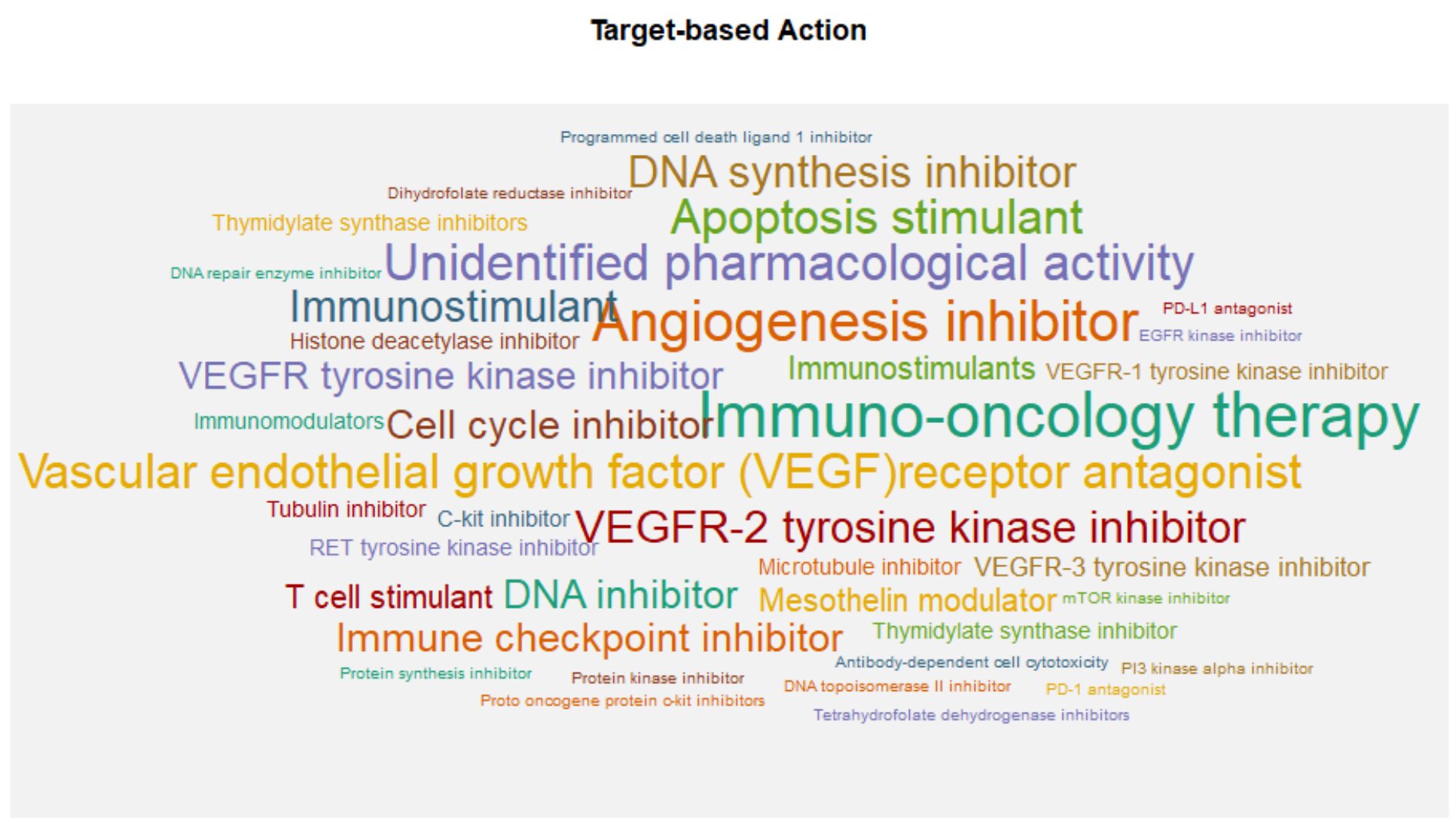
	Trial Title	Primary Drugs - PD1	Primary Drugs	Trial Phase	Trial Status	Target Accrual	Start Date	Primary Completion Date	Trial Tags
1	A Phase III, Open-Label, Multicenter, Randomized Study to Investigate the Efficacy and Safety of Atezolizumab (Anti-PD-L1 Antibody) Compared With Docetaxel in Patients 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

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

Top Drug Targets by number of drugs



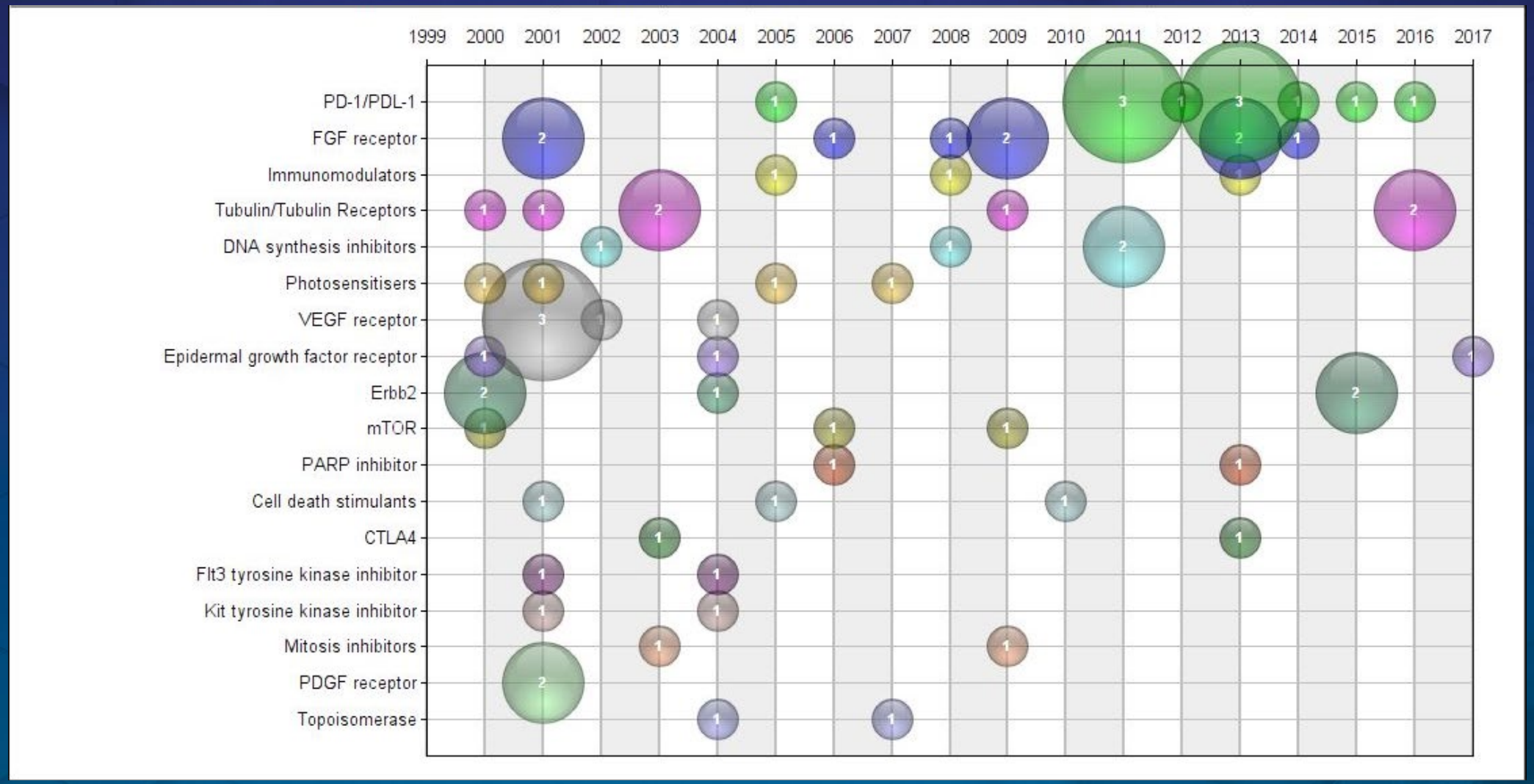
Pipeline landscape: Target novelty sneak peek



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

COVID-19 Vaccines – US, UK, & Europe

Phase 1	Phase 2	Phase 3	In Review	Authorized
CORVax - OncoSec US	**COVIDeVax - Takis/Rottapharm** Italy	**INO 4800 - Inovio** US	**Covovax - Novavax** Australia, EU, UK, US, Canada, NZ	**BNT 162 - BioNTech/Pfizer** Multiple countries including US and EU
MIVAC - Milad Iceland	**VLA2001 - Valneva** UK	**AV-COVID-19 - Aivita** US	**CVnCoV - CureVac** Europe	**mRNA 1273 - Moderna** Multiple countries including US and EU
COVI-VAC - Codagenix UK	**ABNCoV2 - AdaptVac** Netherlands	**SCB 2019 - Clover/GSK** Multiple countries outside of US including EU, Africa, Asia and Latin America	**Sputnik V - Gamaleya** EU, India (Authorized multiple countries(	**Ad26.COV2.S - J&J** US, EU Liechtenstein, Norway, Canada, Iceland
CoVac-1 - Univ Hosp Tuebingen Germany	**KBP-COVID-19 - Kentucky BioProcessing** US	**GRAd-COV2 - ReiThera** Italy		**AZD 1222 - AstraZeneca/Oxford** Multiple countries outside of US including EU, UK, Canada, Mexico
COVAX 19 - GeneCure US, Australia	**SP-0253 - Sanofi/GSK** Panama, US, Honduras	**VLP vaccine - Medicago** US, Canada		
mRNA 1283 - Moderna US	**ARCT-021 - Arcturus** Singapore, US			
mRNA vaccine - GSK/CureVac US	**mRNA-1273.351 - Moderna** US			
SAMLNPS - Gritstone US	**MRT5500 - Translate/Sanofi** US, France			
saRNA vaccine - Imperial Coll London UK	**Ad5 COVID-19 - ImmunityBio** US			
AdCOVID - Altimmune US	**NasoVAX - Altimmune** US			
COH04S1 - City of Hope US				
VXA-CoV2-1 - Vaxart US				

Vaccine type

- DNA
- Inactivated
- Live-attenuated
- modified Antigen-Presenting Cell (APC)
- Protein subunit
- RNA
- Viral vector
- Virus-like particle

Updated April 6, 2021

Source: Adis R&D Insight, Pharmaprojects, Cortellis, GlobalData

Created with VantagePoint – Smart Charts Edition (VP-SCE)

VP-SCE Piano Chart

Piano chart – drugs by indication phase and route of administration

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

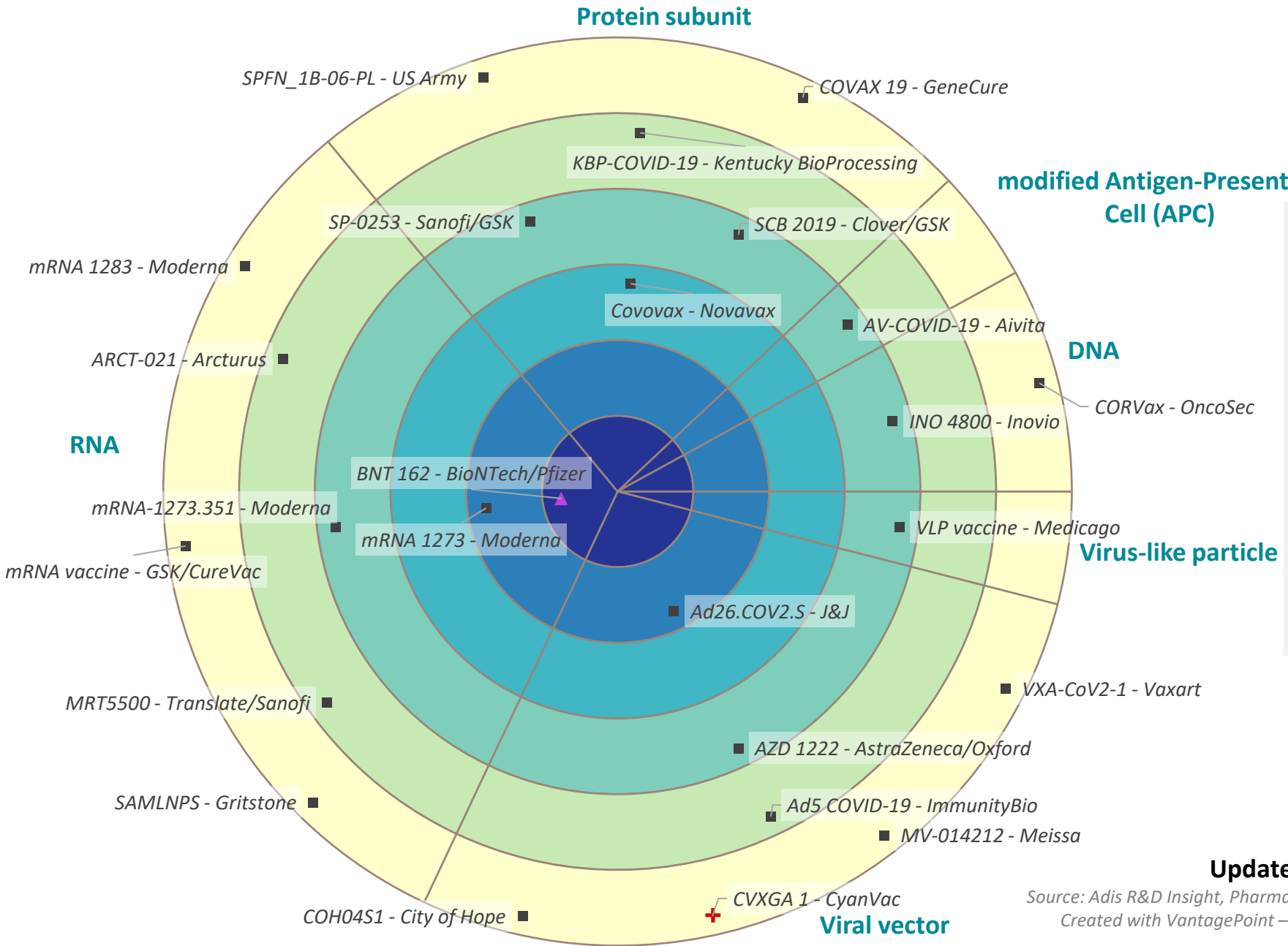
VP-SCE

Piano Chart

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

COVID-19 Vaccines – US

VP-SCE Bullseye℠



Phase 1
Phase 2
Phase 3
In Review
Authorized
Approved

▲ Phase change

✚ New this update

Included: clinical phase or above in the US. Some vaccines are at a higher phase globally.

Software for Business Intelligence

BizInt Smart Charts

Updated September 1, 2021

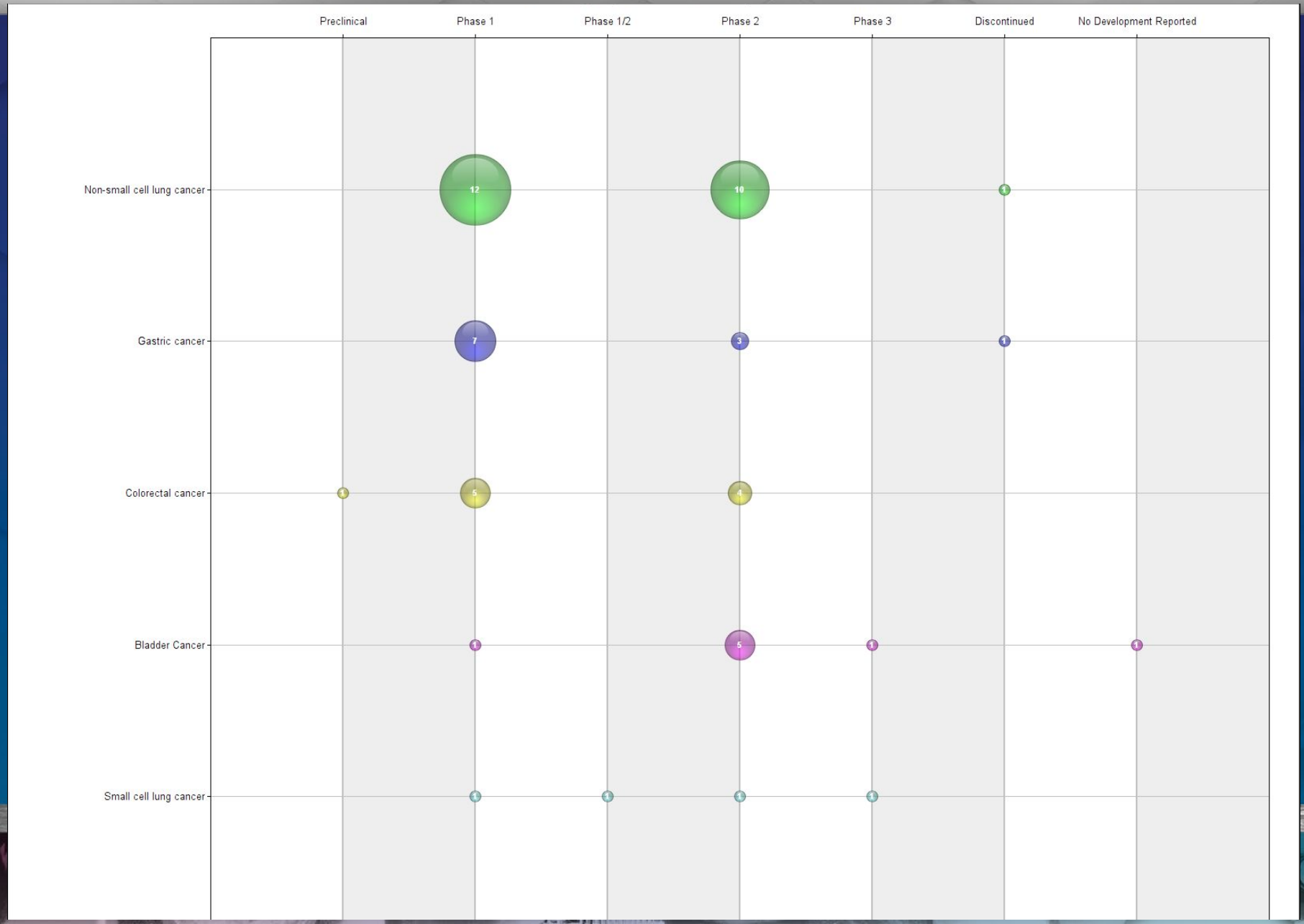
Source: Adis R&D Insight, Pharmaprojects, Cortellis, GlobalData
Created with VantagePoint – Smart Charts Edition (VP-SCE)

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



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

Key Opinion leader clean and extract information – literature and trials

	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

Key Opinion leader metrics – literature with year trendline, regions, and clinical trial lead

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			
Morizane, Chigusa	52			
Ueno, Hideki	52			
Falconi, Massimo	50			
Bassi, Claudio	49			
Atcher, Robert W	47			

Literature:
Identify Abstract sections and extract keywords

Literature: Abstract sections (Method & Results) extracted with 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,

Literature: terms extract from results section with VP-SCE

	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