Review and update of active and passive immunization against respiratory syncytial virus - BioDrugs

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Supplementary table 1: Past, present and future RSV vaccine candidates as per paediatric, maternal, adult, and elderly age groups

Vaccine type	Research Company with Molecule Descriptions	Current and Past Trials	Vaccine trial outcomes as per age group studied	
			Paediatric / Maternal candidates	**Adult / Elderly candidates**
Live attenuated / Chimeric	MedImmune LLC			
	MEDI-559 (rA2cp248/404/1030ΔSH) Intranasal	Phase 1 Phase 2 (N=116)	Safety, tolerability, viral shedding, immunogenicity and genotypic and phenotypic stability Healthy RSV seronegative children (1-<24months) Completed: December 2011 (NCT00767416) Good humoral immune response	N/A
	Pontificia Universidad Catolica de Chile			
	rBCG-N-hRSV Intradermal	Phase 1 (N=24)	N/A	Safety, tolerability and immunogenicity Healthy adult (18-50 years) Completed: June 2018 (NCT03213405) Good safety profile with induction of humoral and specific cellular immune responses
	Blue Lake Biotechnology			
	BLB-201 / CPI-RSV-F (Attenuated canine PIV5 with RSV F protein) Intranasal	Phase 1 (N=30)	N/A	Safety, tolerability, and immunogenicity Healthy adults (18-59 years) Elderly (60-75 years) Started: July 2022 Ongoing (NCT05281263)
	National Institute of Allergy and Infectious Diseases			
	RSV ΔNS2 Δ1313 I1314L Intranasal	Phase 1 (N=105)	Safety and Immunogenicity Child (4-59 months) Started: June 2013 Ongoing (NCT01893554) Immunogenic in RSV-seronegative children	N/A
	RSV LID ΔM2-2 Vaccine Intranasal	Phase 1 (N=29)	Safety and immunogenicity Child (6-24 months) Finished: April 2015 (NCT02237209) Immunogenic in children	N/A
	RSV cps2 Vaccine Intranasal	Phase 1 (N=50)	Safety and immunogenicity Completed: July 2015 (NCT01852266+NCT01968083) Well tolerated and moderately immunogenic	N/A
	RSV MEDI ΔM2-2 Intranasal	Phase 1 (N=60)	Safety and immunogenicity Child (6 months-17 years) + Adult (18-49 years)	

			Completed: August 2015 (NCT01459198)	
	RSV LID cp ΔM2-2 Intranasal	Phase 1 (N=17)	Safety and immunogenicity Child (6-24 months) Completed: April 2017 (NCT02890381) Overattenuated	N/A
	RSV LID ΔM2-2 1030s Vaccine Intranasal	Phase 1 (N=33)	Safety and immunogenicity Child (6-24 months) Completed: July 2017 (NCT02237209+NCT02952339)	N/A
	RSV D46cp ΔM2-2 Intranasal	Phase 1 (N=45)	Safety and immunogenicity Child (6-24 months) Completed: April 2018 (NCT02601612+NCT02601612)	N/A
	D46/NS2/N/ΔM2-2- HindIII Intranasal	Phase 1 (N=32)	Safety and immunogenicity Child (6-24 months) Completed: May 2018 (NCT03102034) Excellent infectivity and immunogenicity	N/A
	RSV ΔNS2/Δ1313/I1314L RSV 6120/ΔNS2/1030s RSV 276 Intranasal		Safety and immunogenicity Children (6-24 months) Started: May 2019 Ongoing (NCT03916185)	N/A
	RSV ΔNS2/Δ1313/I1314L RSV 276 Intranasal	Phase 1 (N=80)	Safety and immunogenicity Child (6-24 months) Completed: September 2020 (NCT03422237+NCT03227029)	N/A
	RSV 6120/ΔNS2/1030s Intranasal	Phase 1 (N=45)	Infectivity, safety and immunogenicity Child (6-60 months) Completed: November 2021 (NCT03387137)	N/A
	RSV 6120/ΔNS1 RSV 6120/F1/G2/ΔNS1 Intranasal	Phase 1 (N=75)	Infectivity, safety and immunogenicity Child (6-59 months) Completed: November 2021 (NCT03596801)	N/A
	RSV LID/ΔM2-2/1030s Intranasal	Phase 1 (N=81)	Infectivity, safety and immunogenicity Child (6-24 months) Started: February 2022 Ongoing (NCT04520659)	N/A
	SeVRSV (Sendai virus vectored RSV vaccine) Intranasal	Phase 1 (N=21)	N/A	Safety and immunogenicity Adults (18-45 years) Completed: February 2019 (NCT03473002)
	Codagenix			

	CodaVax-RSV Intranasal	Phase 1 (N=36)	N/A	Safety, tolerability and immunogenicity Adult (50-75 years) Completed: May 2021 (NCT04295070)
		Phase 1 (N=36)	Safety and immunogenicity Child (6 months – 5 years) Started: March 2022 Ongoing (NCT04919109)	N/A
	Sanofi Pasteur			
	VAD00001 Intranasal	Phase 2 (N=300)	Safety, immunogenicity and dose-finding Children (6-18 months) Started: September 2020 Ongoing (NCT04491877)	N/A
	Meissa Vaccines			
	MV-012-968 (Codon deoptimization of NS1/NS2/G) Intranasal	Phase 1 (N=34)	Safety and immunogenicity Children (15-59 months) Completed: May 2021 (NCT04444284)	N/A
		Phase 1 (N=63)	Safety and Immunogenicity RSV seronegative children (6-36 months) Started: June 2021 Ongoing (NCT04909021)	N/A
		Phase 1 (N=20)	N/A	Safety and Immunogenicity Adults (18-40) Completed: August 2020 (NCT04227210)
		Phase 2 (N=60)	N/A	Safety and prophylactic efficacy Adult (18-45 years) Completed: September 2021 (NCT04690335)
Protein based (Sub-unit)	Novavax			
	RSV F vaccine with and without adjuvant Intramuscular	Phase 1 (N=150)	Safety and tolerability Healthy adults (18-49 years) Completion: 2011 Safe and tolerated	N/A
		Phase 2 (N=330)	Safety and immunogenicity Maternal: Adult females (18-35 years) Completion: May 2013 (NCT01704365) Safe and immunogenic	N/A
		Phase 2 (N=720)	Safety and immunogenicity Maternal: Adult females (18-35 years) Completed: April 2014 (NCT01960686) Safe and immunogenic	N/A
		Phase 2 (N=50)	Safety and immunogenicity, and impact on infants Maternal: Adult females (18-40 years)	N/A

			Completed: July 2016 (NCT02247726) Supportive of maternal immunisation strategy	
		Phase 3 (N=4636)	Safety and efficacy of maternally transferred antibodies in preventing RSV disease in their infants Maternal: Pregnant adult females third trimester (18-40 years) Completed: July 2019 (NCT02624947) Did not meet pre-specified success criterion	N/A
		Phase 1 (N=32)	Immunogenicity and Safety Healthy children (24-72 months) Completed: April 2016 (NCT02296463)	N/A
		Phase 2 (N=1599)	N/A	Immunogenicity and safety Elderly (>60 years) Completed: March 2016 (NCT02266628)
		Phase 2 (N=300)	N/A	Safety and immunogenicity Elderly (60-80 years) Completed: May 2018 (NCT03026348)
		Phase 3 (N=11850)	N/A	Efficacy Elderly (>60 years) Completed: December 2016 (NCT02608502)
	GlaxoSmithKline			
	RSVpreF: GSK3003892A GSK3003893A GSK3003895A GSK3003896A GSK3003898A GSK3003899A Intramuscular	Phase 1 (N=128)	N/A	Safety, reactogenicity and immunogenicity Adult (18-44 years) Completed: March 2015 (NCT01905215) No vaccine induced responses
	RSV subunit with or without adjuvant Intramuscular	Phase 1 (N=288)	N/A	Safety and Immunogenicity Adult (18-45 years) Completed: March 2017 (NCT02298179) Well tolerated and improved neutralizing antibody titers
	RSVpreF GSK3844766A with AS01B adjuvant Intramuscular	Phase 1 (N=40)	N/A	Safety, reactogenicity and immunogenicity Elderly (60-80 years) Completed: December 2020 (NCT04090658)
		Phase 1 (N=1053)	N/A	Safety, reactogenicity and immunogenicity Elderly (60-80 years) Completed: June 2022

				(NCT03814590+NCT04657198) Selected for further development
	RSVPreF3 Intramuscular	Phase 3 (N=1720)	N/A	Immunogenicity, safety, reactogenicity Elderly (>60 years) Started: February 2021 Ongoing (NCT04732871)
		Phase 3 (N=757)	N/A	Safety and reactogenicity Elderly (>60 years) Completed: June 2022 (NCT05059301)
		Phase 3 (N=26665)	N/A	Efficacy Elderly (>60 years) Started: May 2021 Ongoing (NCT04886596)
	RSVpreF3 with AS01 adjuvant co-administered with FLU-QIV vaccine Intramuscular	Phase 3 (N=976)	N/A	Immune Response, safety and reactogenicity Elderly (>60 years) Completed: February 2022 (NCT4841577)
	RSVpreF3 administered with FLU HD vaccine Intramuscular	Phase 3 (N=1028)	N/A	Immune response, safety and reactogenicity Elderly (>65 years) Completed: July 2023 (NCT05559476)
	RSVpreF (GSK3888550A) RSV MAT Intramuscular	Phase 1 (N=502)	Safety, reactogenicity and immunogenicity Maternal: Adult female (18-45 years) Completed: September 2019 (NCT03674177)	N/A
		Phase 2 (N=534)	Safety, reactogenicity and immunogenicity in mother and infants Maternal: Pregnant women (15-40 years) Completed: May 2021	N/A
		Phase 3 (N=369) (N=10640)	Efficacy in preventing RSV associated LRTI in infants Maternal: Pregnant women (15-49 years) Started: November 2020 Ongoing (NCT04605159)	N/A
			Immunogenicity and reactogenicity in mother and infants Maternal: Pregnant women (15-49 years) Completed: June 2022 (NCT04980391)	N/A
	RSVpreF (GSK3003891A) Intramuscular	Phase 1 (N=128)	Safety, reactogenicity and immunogenicity Healthy adults (18-44 years) Completed: March 2015 (NCT01905215)	N/A

		Phase 2 (N=406)	Safety, reactogenicity and immunogenicity Maternal: Female adult (18-40 years) Completed: February 2018 (NCT02956837) Well tolerated and induced neutralizing antibodies	N/A
		Phase 3 (N=102)	Safety, reactogenicity and immunogenicity Female adult (18-45 years) Completed: June 2018 (NCT02753413)	N/A
	RSVpreF3 with or without Diphtheria, Pertussis and tetanus viruses Intramuscular	Phase 2 (N=509)	Primary Dose Maternal: Adult females (18-45 years) Completed: November 2021 (NCT04138056)	N/A
	RSV F protein nanoparticle (RSV MAT) with or without Influenza D-QIV vaccine Intramuscular	Phase 3 (N=1589)	Reactogenicity and immunogenicity Maternal: Non-pregnant women (15-49 years) Completed: June 2022 (NCT05045144)	N/A
	Pfizer			
	RSVPreF	Phase 1+2 (N=1235)	N/A	Safety, tolerability and immunogenicity Healthy adults (18-49 years) Completed: December 2020 (NCT03529773)
		Phase 2 (N=62)	N/A	Safety, Immunogenicity and Efficacy Healthy adults (18-50 years) Completed: April 2021 (NCT04785612) Safe and protective against RSV infection
		Phase 2 (N=1153)	Safety, tolerability and immunogenicity Maternal: Pregnant women (18-49 years) Completed: September 2021 (NCT04032093)	N/A
		Phase 3 (N=10000)	Efficacy and safety of maternally transferred antibodies in preventing RSV disease in their infants Maternal: Pregnant adult females third trimester (18-40 years) Started: June 2020 (NCT04424316)	N/A
		Phase 3 (N=37630)	N/A	Safety, efficacy and immunogenicity (RENOIR) Elderly (>60 years) Started: August 2021 (NCT05035212)
	RSVpreF (3 lots)	Phase 3 (N=993)	N/A	Safety, tolerability and immunogenicity of three lots Healthy adults (18-49 years) Completed: April 2022 (NCT05096208)

	RSVpreF with TDap	Phase 2 (N=713)	Safety, tolerability and immunogenicity Healthy non-pregnant women (18-49 years) Completed: December 2019 (NCT04071158)	N/A
	RSVpreF with SIIV	Phase 1+2 (N=317)	N/A	Safety, tolerability and immunogenicity Healthy adults (18-49 years) Completed: August 2021 (NCT03572062)
		Phase 3 (N=1406)	N/A	Safety, tolerability and immunogenicity Elderly (>60 years) Completed: October 2022 NCT05301322
	MedImmune LLC			
	MEDI-7510 (RSVpostF) Intramuscular	Phase 2 (N=1900)	N/A	Efficacy study Elderly (>60 years) Completed: November 2016 (NCT02508194) Immunogenic, not protective
	Mucosis BV			
	RSV prefusion F subunit linked to a bacterium particle (SynGEM) Intranasal	Phase 1 (N=48)	N/A	Safety and Immunogenicity of 2 Intranasal Doses Adult (18-49 years) Completed: December 2017 (NCT02958540) Persistent antibody response
	Janssen Vaccines			
	Multiple RSVpreF formulations Intramuscular	Phase 1	N/A	Safety and Immunogenicity Elderly (>60 years) Completed: June 2029 (NCT05327816)
	Daiichi Sankyo Co			
	VN-0200 Intramuscular	Phase 1 (N=48)	N/A	Safety, tolerability and immunogenicity Adults and Elderly (20-80 years) Completed: December 2021 (NCT04914520)
		Phase 2 (N=340	N/A	Immunogenicity, safety and tolerability Adults and Elderly (60-80 years) Started: October 2022 Ongoing (NCT05547087)
	Advaccine Biopharmaceuticals			
	BARS13 (rRSV G protein with cyclosporine A) Intramuscular	Phase 1 (N=60)	N/A	Safety and Immune Response Adults (18-45 years) Completed: August 2019 (NCT04851977)
		Phase 2 (N=125)	N/A	Safety and immunogenicity Elderly (60-80 years) Started: May 2021 Ongoing (NCT04681833)

	Virometrix			
	V-306 (Synthetic virus like particles with RSV F-protein site II) Subcutaneous	Phase 1 (N=60)	N/A	Safety and Tolerability Adult (18-45 years) Completed: March 2022 (NCT04519073)
	Dalhousie University			
	DPX-RSV(A) Intramuscularly	Phase 1 (N=40)	N/A	Safety and tolerability Adults (50-64 years) Completed: March 2017 (NCT02472548)
	National Institute for Allergy and Infectious Diseases			
	VRC-RSVRGP084-00-VP Intramuscularly	Phase 1 (N=95)	N/A	Dose, safety, tolerability and immunogenicity Adult (18-50 years) Completed: October 2019 (NCT03049488) Safe and well tolerated Robust specific antibody response with neutralizing activity
Nucleic acid based	Moderna			
	mRNA-1345 Intramuscular	Phase 1 (N=651)	Safety, reactogenicity, and immunogenicity Child, adult, Elderly (12 months-79 years) Started: September 2020 Ongoing (NCT04528719)	
		Phase 3 (N=34000)	N/A	Safety and Efficacy Elderly (>60 years) Started: November 2021 Ongoing (NCT05127434)
	mRNA-1345 combined with SARS-CoV-2, Influenza and CMV mRNA vaccines Intramuscular	Phase 1 (N=300)	N/A	Safety, reactogenicity and immunogenicity Healthy adults (18-75) Started: May 2022 Ongoing (NCT05397223)
	mRNA-1345 combined or separate with Influenza, and SARS-CoV-2 vaccines Intramuscular	Phase 1 (N=675)	N/A	Reactogenicity, and immunogenicity of multi-component vaccines Adult and Elderly (50-75) Started: October 2022 Ongoing (NCT05585632)
Vector based Vaccines	MedImmune LLC			
	MEDI-534 (hPIV3 F protein, hPIV3 HN, RSV F protein) Intranasal	Phase 1 (N=120)	N/A	Dose-Escalating Study Healthy Adults (18 – 40 years) Completed: 2005 (NCT00111878) No subjects experienced a fourfold increase in serum RSV titers
		Phase 1 (N=49)	Evaluate the Safety, tolerability, immunogenicity, and viral Shedding	N/A

			Children (6-24 months) Completed: April 2010 (NCT00493285) Supports continued development	
		Phase 1 (N=1338)	Safety and tolerability of multiple doses Children (6-24 months and 2 months) Completed August 2012 (NCT00686075)	N/A
	Janssen Vaccines			
	Ad26.RSV.preF Intramuscular	Phase 1 (N=48)	Safety, tolerability and immunogenicity Children (12-24 months) Adults (18-50 years) Completed: April 2020 NCT03303625	N/A
		Phase 2 (N=64)	N/A	Efficacy of a single immunization Adults (18-50 years) Completed: July 2018 (NCT03334695)
		Phase 1 (N=38)	Safety and reactogenicity Children (12-24 months) Completed: November 2021 NCT03606512	N/A
		Phase 1 (N=73)	N/A	Safety and tolerability of 2 single doses of either approximately 12 months apart Elderly (>60 years) Completed: January 2019 (NCT02926430)
		Phase 2 (N=459)	N/A	Range of dose levels Elderly (>60 years) Completed: April 2021 (NCT04453202)
		Phase 2 (N=5815)	N/A	Efficacy, immunogenicity and safety Elderly (>65 years) Started: August 2019 Ongoing (NCT03982199)
		Phase 3 (N=27500)	N/A	Efficacy Study (EVERGREEN) Elderly (>60 years) Started: July 2021 Ongoing (NCT04908683)
		Phase 3 (N=2180)	N/A	Efficacy, safety, reactogenicity, and immunogenicity Adults (20-59 years) Elderly (>60 years) Started: April 2022 Ongoing (NCT05242432)
		Phase 3	N/A	Safety and Immunogenicity Adult (18-64 years) Elderly (>65 years)

				Completed: August 2022 (NCT05070546)
	GlaxoSmithKline			
	ChAd155-RSV Intramuscular	Phase 1 (N=73)	N/A	Safety, reactogenicity and immunogenicity Adults (18-45 years) Completed: January 2017 (NCT02491463) Generated specific humoral and cellular immune responses in adults previously exposed to natural RSV
		Phase 1 (N=107)	Safety, reactogenicity and immunogenicity Child (12-23 months) Completed: February 2019 (NCT02927873)	N/A
		Phase 1 (N=201)	Safety, reactogenicity and immunogenicity Child (6-7 months) Completed: July 2021 (NCT03636906)	N/A
	Vaxart			
	VXA-RSV-f (Adenoviral vector based RSV F vaccine with dsRNA adjuvant) Oral	Phase 1 (N=66)	N/A	Safety and Immunogenicity Adults (18-49 years) Completed: September 2017 (NCT02830932)
	ReiThera Srl			
	PanAd3-RSV (Simian adenovirus with F, N and M2-1 protein) MVA-RSV (Modified Vaccinia virus Ankara with F,N and M2-1 protein) Intramuscular	Phase 1 (N=72)	N/A	Safety and Immunogenicity Adult (18-75 years) Completed: August 2015 (NCT01805921) Safe and immunogenic
	Bavarian Nordic			
	MVA-BN-RSV Intramuscular	Phase 1 (N=63)	N/A	Safety, tolerability and immunogenicity Adult (18-65 years) Completed: May 2016 (NCT02419391)
		Phase 2 (N=420)	N/A	Safety, and immunogenicity Elderly (>55 years) Completed: December 2018 (NCT02873286) Broad spectrum immune response
		Phase 3 (N=20000)	N/A	Clinical efficacy, safety and reactogenicity Elderly (>60 years) Started: April 2022 Ongoing (NCT05238025)