Clinical Trials Update:

Outcomes from Interventional Studies for Key Drugs Studied by TFORD

Data updated as of 30th November 2020

Summary

- Slides summarize details of interventional clinical studies with their outcomes for 11 key drugs studied by TFORD
- Only interventional studies have been included in this update
- Data is updated with studies published/released till 30th Nov 2020
- Detailed information regarding clinical studies and data for other drugs studied by TFORD are listed here - https://docs.google.com/spreadsheets/d/1HNv1iP4U1r5HsQR1kp-5a81szR222tIi0ipIDv75k8U/edit?usp=sharing
- For more information regarding drugs studied by TFORD please visit - http://www.nclinnovations.org/covid19/

List of Drugs Reviewed

Update on previously reviewed drugs:

- Hydroxychloroquine
- Remdesivir
- Tocilizumab
- Favipiravir
- Umifenovir
- Dexamethasone
- IFN-β

New in this update:

- Itolizumab
- Casirivimab/ Imdevimab
- Methyl Prednisolone
- Baricitinib

Update March to June 2020

Clinical Data Update

Drug # Hydroxychloroquine (Page 1 of 2)

Drug	Type	Route of Administration	Approved for COVID-19	
			India	Others
Hydroxychloroquine (HCQ)	AV	Oral	Yes (P)	No

Study ^	Location	Study Type	Population Size	Stage	Dose	Outcome (TFORD View)
Gautret et al	France	NR; T	36	Mild	HCQ - Oral/600mg/TID/10D HCQ+ AZT - Oral/500mg-D1 /250mg/QD/4D	**Positive Effect**
Chen Jun et al	China	RT; T	30	Moderate	HCQ-Oral/400mg/QD/5D	**No effect**
Lee et al	China	NA; P	211	COVID-ve; Exposed	HCQ- 400mg/QD/14D	**Inconclusive due to to lack of controls**
Boulware et al	USA	RT; P	821	COVID-ve; Exposed	HCQ- 800 mg+600mg/QD/D1, 600 mg QD/4D	**No effect**
Tang et al	China	RT; T	150	Mild/Moderate/ Severe	HCQ-1200 mg/QD/3D; 800 mg/QD/14D-21D	**No effect**
Torjesen et al (Recovery Trial)	UK	RT; T	4764	Hospitalized	HCQ – 10 days; Dose data not available	**No effect (Interim data)**
Chen et al	China	RT; T	48	Moderate	HCQ - 200 mg/ BID/10D	**No effect**
Cavalcanti et al	Brazil	RT; P & T	667 (504 COVID+ve)	COVID-ve; Mild/Moderate	HCQ - 400 mg/BID/7D HQ + AZT - 400 mg/BID+ 500 mg/QD/7D	**No effect**
Skipper et al	USA, Canada	RT; P & T	395	COVID-ve exposed, COVID+ve Mild	HCQ- 800 mg+600mg/QD/D1, 600 mg QD/4D	**No effect**

Published | Pre-prints/Press release/Others

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Data for interventional trials updated till 20th July 2020

Update - July to Nov 2020

Clinical Data Update

Drug # Hydroxychloroquine (Page 2 of 2)

Drug	Type	Route of Administration	Approved for COVID-19	
			India	Others
Hydroxychloroquine (HCQ)	AV	Oral	Yes (P)	No

Study ^	Location	Study Type	Population Size	Stage	Dose	Outcome (TFORD View)
Pan (2020) WHO Solidarity	405 sites, 30 countries	RT;T	11330 (947 HCQ with 906 controls)	NA	HCQ- 400 mg BID/D1; 400 mg QID 9 days	No Effect (Interim Data)
Rahmani (2020)	Iran	NR;T	110	Moderate to severe	HCQ - 400 mg BD/D1; 200 mg BD/D1-D7 Atazanavir/Ritonavir –300mg/100mg/D1-D7	Inconclusive due to lack of controls
Chen (2020)	China	RT;T	62	Hospitalised	HCQ-Oral/400mg/OQ/1-5days	Positive Effect
Mitja (2020)	Spain	RT;P	2314	COVID-19-ve; Exposed	HCQ- 800mg once, 400mg/QD/6 days	No effect

Published Pre-prints/Press release/Others

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Drug # Remdesivir (Page 1 of 2)

Drug	Type	Route of Administration	Approved for COVID-19	
			India	Others
Remdesivir (RDV)	AV	Injectable	Yes (T)	Yes (T) (USA, UK, Japan)

Study ^	Location	Study Type	Population Size	Stage	Dose	Outcome (TFORD View)
Grein et al	9 countries	NR; T	53	Severe	RDV- 200mg/D1; 100mg/QD/9D	**Positive effect**
Spinello et al	Italy	NR; T	35	Severe	RDV- 200mg/D1; 100mg/QD/ 9D	**Inconclusive due to to lack of controls**
Beigel et al	US	RT; T	1063	NA	RDV- 200mg/D1; 100mg / QD/9D	**Positive effect (Interim Data)**
Goldman et al	US	RT; T	397	Severe	RDV- 200mg/D1; 100mg/ QD/9D	**No effect (Interim data)**
Gilead Announcement	180 sites; 15 countries	RT; T	NA	Moderate	RDV- 5 or 10 day treatment; Dose data not available	**Positive effect (5D)**
Wang et al	China	RT; T	237	Moderate	RDV- 200mg/D1; 100mg/ QD/2-10D	**No effect**

Published **Pre-prints/Press release/Others**

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Data for interventional trials updated till 20th July 2020

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Drug # Remdesivir (Page 2 of 2)

Drug	Type	Route of Administration	Approved for COVID-19	
			India	Others
Remdesivir (RDV)	AV	Injectable	Yes (T)	Yes (T) (USA, UK, Japan)

Study ^	Location	Study Type	Population Size	Stage	Dose	Outcome (TFORD View)
Spinner (2020)	105 sites, 3 countries	RT;T	584	Moderate	RDV- 200mg/D1; 100mg/QD; 5 or 10 days	**Positive Effect (5D)**
Pan (2020) WHO Solidarity	405 sites, 30 countries	RT;T	11330 (2743 RDV/2708 control)	NA	RDV- 200mg/D1; 100mg / QD/9D	**No effect**
Beigel (Final report 2020)	60 sites, 10 countries	RT;T	1062	Patients with lower respiratory tract involvement	RDV- 200mg/D1; 100mg / QD/9D	**Positive Effect**

Published **Pre-prints/Press release/Others**

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Data for interventional trials updated till 20th Nov 2020

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Drug # Tocilizumab (Page 1 of 2)

Drug	Type	Route of Administration	Approved for COVID-19	
			India	Others
Tocilizumab (TCZ)	AI	Injectable	No (CM)	No (CM)

Study ^	Location	Study Type	Population Size	Stage	Dose	Outcome (TFORD View)
Morena et al	Italy	NR; T	51	Severe	TCZ-35% -400mg/BID; 65% - 8mg/kg/BID	**Inconclusive due to lack of controls**
Montalava et al	Spain	NR; T	82	Severe	TCZ- 400mg or 600mg /Once	**Inconclusive due to lack of controls**
Perrone et al	Italy	NR; T	1221	Moderate/Severe	TCZ-8 mg/kg/QD or BID	**Positive effect**
Sciascia et al	Italy	NR; T	63	Severe	TCZ-8 mg/kg/Once or twice	**Positive effect**
Stohbehn et al	USA	NR; T	32	Mild/Moderate	TCZ- Group A- 200mg/120 mg/once TCZ- Group B- IV/80mg/once	**Positive effect**
Roche Press Release (COVACTA)	NA	RT; T	450	Severe	TCZ- 8 mg/kg, up to a maximum dose 800 mg	**No effect**

Published **Pre-prints/Press release/Others**

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Data for interventional trials updated till 20th July 2020

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Drug # Tocilizumab (Page 2 of 2)

Drug	Type	Route of Administration	Approved for COVID-19	
			India	Others
Tocilizumab (TCZ)	AI	Injectable	No (CM)	No (CM)

Study ^	Location	Study Type	Population Size	Stage	Dose	Outcome (TFORD View)
Stone (2020)	USA	RT;T	243	Moderate/Severe	TCZ single dose 8 mg /kg IV, not to exceed 800mg	**No effect**
Press release Empacta Phase III	United States, South Africa, Kenya, Brazil, Mexico and Peru.	RT;T	389	COVID-19 Pneumonia	TCZ 8 mg/kg, with a maximum dose of 800 mg	**Positive Effect**
Malekzadeh (2020)	Iran	NR;T	126	Severe	TCZ SC 324 mg or 486 mg +SOC	**Inconclusive due to lack of controls**

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Drug # Favipiravir (Page 1 of 2)

TFORD COVID19 India

Drug	Type	Route of Administration	Approved for COVID-19	
			India	Others
Favipiravir (FPV)	AV	Oral	Yes (T)	Yes (T) (Russia)

Study ^	Location	Study Type	Population Size	Stage	Dose	Outcome (TFORD View)
Cai et al	China	NR; T	80	Mild/Moderate	FPV -1600mg/BID/D1; 600mg /BID/D2-14	**Positive effect**
Chang Chen et al	China	RT; T	240	NA	FPV- 1600 mg/BID/D1; 600 mg/BID/D2 –D7,10 UFV-200mg/TID/7-10D	**No effect**
Lou et al	China	RT; T	30	Mild	FPV- 1600 mg or 2200mg/ D1 /600mg/TID/D5-D14 Baloxavir- 80mg/QD/D1,7,14	**No effect**
Glenmark Press Release	India	RT; T	NA	Mild/Moderate	FPV- 3,600 mg (1,800 mg BID) D1 + 1,600 mg (800 mg BID) (D2 or later)/14D	**Positive effect**

Published **Pre-prints/Press release/Others**

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Data for interventional trials updated till 20th July 2020

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Drug # Favipiravir (Page 2 of 2)

Drug	Type	Route of Administration	Approved for COVID-19	
			India	Others
Favipiravir (FPV)	AV	Oral	Yes (T)	Yes (T) (Russia)

Study ^	Location	Study Type	Population Size	Stage	Dose	Outcome (TFORD View)
Yamamura (2020)	Japan	NR; T	13	Moderate/Severe	FPV- 3600 mg/D1, 1600 mg/D2 to D14 Methylprednisolone – 1000mg/3 days starting from D5 of FPV administration LMWH-2000 IU/every 12hrs	**Inconclusive due to lack of controls**
Doi (2020)	Japan	NR;T	11	Severe	FPV- 3600 mg/D1, 1600 mg/D2 to D14 Nafomastat Mesylate – 0.2mg/hr/kg body weight/14 days	**Inconclusive due to lack of controls**
Biospectrum Asia News release	Japan	NR;T	156	NA	NA	**Positive Effect**
Ivashchenko (2020)	Russia	RT;T	60	Moderate to severe	FPV- 1600 mg BID/D1; 600 mg BID D2 to D14 FPV- 1800 mg BID/D1; 800 mg BID D2 to D14	**Positive Effect**

Published **Pre-prints/Press release/Others**

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Data for interventional trials updated till 20th Nov 2020

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Drug # Umifenovir (Page 1 of 2)

Drug	Type	Route of Administration	Approved for COVID-19	
			India	Others
Umifenovir (UFV)	AV	Oral	No	No

Study ^	Location	Study Type	Population Size	Stage	Dose	Outcome (TFORD View)
Li et al	China	RT; T	44	Mild/Moderate	UFV-100mg/TID/7-14D Lopinavir/Ritonavir-200mg-50mg/BID/7-14D	**No effect**
Chang Cheng et al	China	RT; T	240	NA	UFV-200mg/TID/7-10D FPV- 1600 mg/BID/D1; 600 mg/BID/D2 –D7,10	**No effect**

Published **Pre-prints/Press release/Others**

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Data for interventional trials updated till 20th July 2020

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Drug # Umifenovir (Page 2 of 2)

Drug	Type	Route of Administration	Approved for COVID-19	
			India	Others
Umifenovir (UFV)	AV	Oral	No	No

Study ^	Location	Study Type	Population Size	Stage	Dose	Outcome (TFORD View)
Wenyu Chen (2020)	China	NR; T	62	NA	UFV 0.2g/TID	**Positive Effect**
Vityala (2020)	Bishkek, Kyrgyzstan	RT;T	30	Mild to Moderate	UFV 200 mg TID/D1 to D5	**Positive Effect**

Published **Pre-prints/Press release/Others**

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Data for interventional trials updated till 20th Nov 2020

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Drug # Dexamethasone (Page 1 of 2)

Drug	Type	Route of Administration	Approved for COVID-19	
			India	Others
Dexamethasone (DEX)	AI	Oral	No (CM)	Yes (T) (UK)

Study ^	Location	Study Type	Population Size	Stage	Dose	Outcome (TFORD View)
Horby et al (RECOVERY Trial)	UK	RT; T	6425	NA	DEX - 6 mg/QD/upto 10D	**Positive effect (Interim Data)**

Published **Pre-prints/Press release/Others**

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Drug # Dexamethasone (Page 2 of 2)

Drug	Type	Route of Administration	Approved for COVID-19	
			India	Others
Dexamethasone (DEX)	AI	Oral	No (CM)	Yes (T) (UK)

Study ^	Location	Study Type	Population Size	Stage	Dose	Outcome (TFORD View)
Tomazini (2020) CoDEX trial	Brazil	RT; T	299	Moderate to severe	DEX 20mg IV 5 days/DEX 10mg 5 days or until ICU discharge	**Positive Effect**

Published **Pre-prints/Press release/Others**

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Drug # IFN-β (Page 1 of 2)

TFORD COVID19 India

Drug	Type	Route of Administration	Approved for COVID-19	
			India	Others
Interferon Beta (IFN-β)	AI	Injectable	No	No

Study ^	Location	Study Type	Population Size	Stage	Dose	Outcome (TFORD View)
Davoudi-Monfared et al	Iran	RT; T	81	Hospitalized /Severe	IFN-β-1a- 44 micrograms/ml (12 million IU/ml)/SC/TID/14D	**Positive effect**
Synairgen Press Release	UK	RT; T	101	Hospitalized	SNG001 – Inhaled version of IFN-B-1a Dose - NA	**Positive effect**

Published **Pre-prints/Press release/Others**

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Drug # IFN-β (Page 2 of 2)

Drug	Type	Route of Administration	Approved for COVID-19	
			India	Others
Interferon Beta (IFN-β)	AI	Injectable	No	No

Study ^	Location	Study Type	Population Size	Stage	Dose	Outcome (TFORD View)
Dastan (2020)	Iran	NR;T	20	Severe	IFN-B-SC/44 µg (equivalent to 12 million IU/QD/D1-10 + SOC – HCQ, LPV/R	**Inconclusive due to lack of controls**
Ivan Fan-Ngai Hung (2020)	Hong Kong	RT;T	127	NA	Interferon beta-1b 8 million IU/0.25 mg/ alternate days for 3 days Ribavirin – 400mg/12hours LPV/R – 400mg/100mg/12 hours/14 days SOC – LPV/R	**Positive Effect**
Pan (2020) WHO Solidarity	405 sites, 30 countries	RT;T	11330 (2063 IFN-B)	NA	IFN ß1a SC44 µg for a total of 3 doses in 6 days (day 1, day 3, day 6	**No Effect**
Rahmani (2020)	Iran	RT;T	66	Severe	IFN β-1b 250 mcg SC every other day for two consecutive weeks + SOC	**Positive Effect**

Published **Pre-prints/Press release/Others**

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Drug # Itolizumab

Drug	Type	Route of Administration	Approved for COVID-19	
			India	Others
Itolizumab (ITZ)	AI	Injectable	Yes (not used in CM)	No

Study ^	Location	Study Type	Population Size	Stage	Dose	Outcome (TFORD View)
Biospectrum News release	India	RT;T	30	Moderate to severe	NA	**Positive Effect**

Published **Pre-prints/Press release/Others**

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TFORD COVID19 India

Drug # Casirivimab & Imdevimab (REGEN CoV2)

Drug	Type	Route of Administration	Approved for COVID-19	
			India	Others
Casirivimab & Imdevimab	Antibody	Injectable	No	Yes (T) (USA)

Study ^	Location	Study Type	Population Size	Stage	Dose	Outcome (TFORD View)
Regeneron	USA	RT;T	275	Mild to Moderate	REGN10933+REGN10987 one-time infusion of 2.4 grams REGN10933+REGN10987 one-time infusion of 8 grams	**Positive Effect**

Published Pre-prints/Press release/Others

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Note: Regeneron consists of 2 novel antibodies targeted against SARS-CoV-2. Included in this update as it has received EUA in the US for COVID-19 for therapy. TFORD is also tracking developments of Bamlanivimab, a novel antibody targeted against SARS-CoV-2, which has received EUA in the US for COVID-19.
https://investor.lilly.com/news-releases/news-release-details/lillys-neutralizing-antibody-bamlanivimab-ly-cov555-receives-fda

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Drug # Methyl Prednisolone

Drug	Type	Route of Administration	Approved for COVID-19	
			India	Others
Methyl Prednisolone (MP)	Steroid	Injectable	No (CM)	No

Study ^	Location	Study Type	Population Size	Stage	Dose	Outcome (TFORD View)
Coral Gudino (2020)	Spain	RT (Partial);T	85	NA	MP [40mg/12h 3 days, then 20mg/12h 3 days]	**Positive Effect**

Published **Pre-prints/Press release/Others**

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Drug # Baricitinib

Drug	Type	Route of Administration	Approved for COVID-19	
			India	Others
Baricitinib (BTN)	AI	Oral	No	Yes (T) (USA)

Study ^	Location	Study Type	Population Size	Stage	Dose	Outcome (TFORD View)
Cantini (2020)	Italy	NR;T	12	Mild to Moderate	BTN- 4mg/QD/14days LPV/r- 250mg/QD/14D	**Positive Effect**
Cision PR Newswire ACTT-2 Trial	USA	RT; T	1034	Hospitalized	RDV- 200 mg /D1; 100mg/QD, upto 10D Baricitinib – PO/4mg/QD/upto 14D (Control Arm– RDV Alone)	**Positive Effect**

Published **Pre-prints/Press release/Others**

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