



Task Force on Repurposing of Drugs (TFORD) for COVID-19

S&T Core Group on COVID19 constituted by PSA to GoI



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Office of Principal Scientific Adviser
to the
Government of India

TFORD-COVID19-India Update as of 15 May 2020

For TFORD-COVID19-India Advisory Group Only | Not for Circulation



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TFORD Admin/Decision/Reporting Timelines:

- ◆ 16 March 2020: First email + call from PSA to GoI
- ◆ 18 March 2020: Proposal submitted
- ◆ 19 March 2020: Constitution of the Empowered Committee for COVID19 Response
- ◆ 21 March 2020: 1st Meeting of the Empowered Committee
- ◆ 23 March 2020: Approval communicated ("Speeding up the Lab to Market Journey: Repurposing Drugs for COVID-19")
- ◆ 28 March 2020: Creation of AG
- ◆ 30 March 2020: Update 1 to PSA
- ◆ 4 April 2020: Proposal submitted to DSIR A2K+
- ◆ 6 April 2020: Update 2 to PSA
- ◆ 17 April 2020: Update 3 to PSA
- ◆ 26 April 2020: Update 4 to PSA
- ◆ 8 May 2020: DSIR Sanction Order



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Timelines of key outputs:

- ◆ 30 March 2020: DP1 released to AG
- ◆ 4th April 2020: AG Meeting for DP1 held
- ◆ 5th April 2020: Molecule Briefs for 6 DP1 candidates, IP Assessment framework released on TFORD site
- ◆ 6th April 2020: Update 2 to PSA about DP 1 and Assessment Framework
- ◆ 12th April 2020: DP2 released to AG
- ◆ 15th April 2020– AG Meeting for DP2 held
- ◆ 18th April 2020 – Molecule Briefs for 13 DP2 candidates released on TFORD site
- ◆ 18th April 2020 – Update 3 to PSA about DP2
- ◆ 25th April 2020 – Heat maps released to AG
- ◆ 26th April 2020 – Heat Maps and De-risking Scores, Drug Monitor released on TFORD site
- ◆ 26th April 2020 - Update 4 to PSA about Heat Maps, Drug Monitor
- ◆ 1st May 2020: Retrospective Trial > Idea initiated
- ◆ 11th May 2020: Indian Clinical Trials Tracker released on TFORD site
- ◆ 14th May 2020: Retrospective Trial > EC Approval
- ◆ 14th May 2020: DP3 released to AG
- ◆ 15th May 2020: AG Meeting for DP3 & TFORD Updates held



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TFORD - COVID19 ADVISORY GROUP

Anurag Agrawal	Atanu Basu	Anant Bhan	Narendra Chirmule	Madhu Dikshit	Santosh Dixit	Chetan Gadgil
Ravindra Ghooi	Sambuddha Ghosh	Nithya Gogtay	Raman Govindarajan	Mukund Gurjar	Chitra Lele	Madhur Motwani
Shridhar Narayanan	Gopakumar Nair	Venkata Palle	Jai Prakash	Ravishankar Ramachandran	D. S. Reddy	Arvind Sahu
Sundeep Salvi	Chaitanya Saxena	Umesh Shaligram	Shankar Subramanian	Premnath Venugopalan		



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TFORD - COVID19 TEAM

 Navnath Kadam	 Smita Kale	 Mugdha Lele
 Priya Nagaraj	 Manisha Premnath	 Tejas Shah
 Premnath Venugopalan	 Vidula Walimbe	 Kirtee Wani



TFORD-COVID19
INDIA



VENTURE
CENTER

TFORD - COVID19 TEAM



Navnath Kadam



Smita Kale



Mugdha Lele



Priya Nagaraj



Manisha Premnath



Tejas Shah



Premnath Venugopalan



Vidula Walimbe



Kirtee Wani



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Work Components



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Information, databases

- Molecule Briefs: 19
- Global CTs reporting results
- CTs (interventional) in India
- Drug Monitor
- Herb Briefs: 9
- Molecule Briefs: 10+10
- Services supporting drug development
- In silico leads
- Updation schedule and versioning

Assessment + frameworks

- AF2: Taking decisions on patent barriers
- Readiness Score and Drug Potential Score
- Heat map 1: Drug Readiness & Potential
- Heat map 2: Patent strategy
- Heat map 3: CT results
- AF1: TRLs, Readiness, Potential
- AF3: Manufacturability, scalability, supply chains
- New leads

Consultation + Networks

- Inter-disciplinary Advisory Group
- Structured discussions: DP1, DP2, DP3
- Sub-Group 1: Therapeutic strategy/ Clinicians
- Sub-Group 2: Retrospective Study
- Industry Group
- Drug translation network
- Structured discussions: DP4, DP5
- Sub-Group 3: CT simulation?



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Position/ Strategy Paper

- SP1: Solidarity Trials
- SP2: Therapeutic Strategies
- SP3: Trial design for India
- Commentary/ position papers/ publications?
- Newspaper OpEds?

Recommendations, Action, Studies

- Retrospective Study
- Priority Drugs for CTs (for Luv Agarwal, JS, MoHFW)
- Suggestions 1
- Real-time data/inputs from medical doctors?

Visibility

- Website
- SM: Twitter, LinkedIn
- Media coverage
- Mailings to KOLs



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Discussion Paper 3: Medicinal Herbs

1. *Tinospora cordifolia*
2. *Glycyrrhiza glabra*
3. *Withania somnifera*
4. *Zingiber officinale*
5. *Andrographis paniculata*
6. *Artemisia annua*
7. *Cissampelos pareira*
8. *Vitis vinifera*
9. *Myrica cerifera*



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Discussion Paper 4

1. Baricitinib (JAK inhibitor)
2. Tofacitinib (JAK inhibitor)
3. Sarilumab (Anti-IL6R Antibody)
4. Lisinopril (ACE Inhibitor)
5. Losartan (ARB inhibitor)
5. Recombinant ACE Protein
6. Dexamethasone (Corticosteroid)
7. Nitazoxanide (Thiazolide)
8. Sepsivac/Mw (Heat killed *Mycobacterium w*)
9. Famotidine (H2R antagonist)
10. Enoxaparin (LMWH)

TFORD will look at 10 candidates in DP-5



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Summary Insights



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	Readiness of the drug candidate for COVID19 for India								Drug potential for India			
Scoring Scale	See Section B for scoring scale	See Section C for scoring scale	See Section D for scoring scale	See Section E for scoring scale	See Section F for scoring scale	See Section G for scoring scale	See Section H for scoring scale		See Section K for scoring scale		Scoring Scale	
Drug candidate	Strength of scientific evidence on mechanism of action	Importance of mechanism of action and target	Strength of results at pre-clinical stage	Availability of Human Safety Data demonstrated through clinical studies	Clarity and certainty on formulations, method of administration, drug delivery and bioavailability for COVID19	Progress of clinical trials for COVID-19 (*outcomes as concluded by authors of published data)	Clarity and degree of certainty about supply chain and manufacturability in India	SCORE: READINESS (for India)	Outcome of clinical trials	SCORE: DRUG POTENTIAL (for India)	Drug candidate	
Chloroquine	3	4	4	5	3	4	5	79%	2	54%	Chloroquine	
Hydroxychloroquine	3	4	4	5	3	5	5	81%	2	54%	Hydroxychloroquine	
Remdesivir	3	5	4	3	2	2	3	68%	No data yet	Awaiting CT data	Remdesivir	
Lopinavir/Ritonavir	3	5	3	5	4	3	5	78%	1	34%	Lopinavir/Ritonavir	
Favipiravir	3	5	4	5	4	4	3	79%	4	73%	Favipiravir	
Baloxavir Marboxil	2	1	3	5	2	2	3	46%	No data yet	Awaiting CT data	Baloxavir Marboxil	
Darunavir	2	2	2	5	4	3	5	61%	1	34%	Darunavir	
Ribavirin + IFN beta	3	2	2	4	4	2	3	55%	No data yet	Awaiting CT data	Ribavirin + IFN beta	
Galidesivir	2	4	3	2	1	1	1	35%	No data yet	Awaiting CT data	Galidesivir	
Oseltamivir	2	1	2	5	4	2	5	52%	1	34%	Oseltamivir	
Umifenovir(**)	3	4	3	5	4	4	1	62%	3	42%	Umifenovir	
Camostat mesylate	4	5	4	5	4	2	1	63%	No data yet	Awaiting CT data	Camostat mesylate	
Ruxolitinib	4	4	2	5	4	2	3	65%	No data yet	Awaiting CT data	Ruxolitinib	
Interferon beta	4	4	3	5	4	2	3	69%	No data yet	Awaiting CT data	Interferon beta	
Tocilizumab	4	5	3	5	4	4	3	79%	4	73%	Tocilizumab	
Ustekinumab	1	1	1	5	1	1	3	29%	No data yet	Awaiting CT data	Ustekinumab	
Nigericin	2	3	2	1	1	1	2	31%	No data yet	Awaiting CT data	Nigericin	
Teicoplanin	4	4	4	5	1	1	5	57%	No data yet	Awaiting CT data	Teicoplanin	
Ivermectin	3	3	4	5	1	1	5	53%	No data yet	Awaiting CT data	Ivermectin	

Source: TFORD-COVID19-India (c) Venture Center, 2020

(**) CT for prophylaxis



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Do patent barriers exist and how strong are they?							
Drug candidate	There are valid active patents in India for basic composition/ formulation/ processes (Yes -1; No -0)	Basic composition of API is protected in India with valid active patents (Yes -1; No -0)	Basic (Innovator's) process of manufacture of API is protected in India with valid active patents (Yes -1; No -0)	Basic (Innovator's) formulation/ drug product (not API) is protected in India with valid active patents (Yes -1; No -0)	Patent barriers exist? (Yes -1; No -0)	Strength of patent barriers (higher% means Higher barriers; weightage for composition is higher)	Drug candidate
Chloroquine	0	0	0	0	0	0%	Chloroquine
Hydroxychloroquine	0	0	0	0	0	0%	Hydroxychloroquine
Remdesivir	1	1	1	1	1	100%	Remdesivir
Lopinavir/Ritonavir	0	0	0	0	0	0%	Lopinavir/Ritonavir
Favipiravir	1	0	1	1	1	50%	Favipiravir
Baloxavir Marboxil	1	1	1	1	1	100%	Baloxavir Marboxil
Darunavir	0	0	0	0	0	0%	Darunavir
Ribavirin + IFN beta	0	0	0	0	0	0%	Ribavirin + IFN beta
Galidesivir	0	0	0	0	0	0%	Galidesivir
Oseltamivir	0	0	0	0	0	0%	Oseltamivir
Umifenovir	0	0	0	0	0	0%	Umifenovir
Camostat mesylate	0	0	0	0	0	0%	Camostat mesylate
Ruxolitinib	1	1	1	1	1	100%	Ruxolitinib
Interferon beta	0	0	0	0	0	0%	Interferon beta
Tocilizumab	0	0	0	0	0	0%	Tocilizumab
Ustekinumab	1	1	1	1	1	100%	Ustekinumab
Nigericin	0	0	0	0	0	0%	Nigericin
Teicoplanin	0	0	0	0	0	0%	Teicoplanin
Ivermectin	0	0	0	0	0	0%	Ivermectin

Source: TFORD-COVID19-India (c) Venture Center, 2020



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Is there a need for Govt action to provide FTO for Indian manufacturers?								
Drug candidate	Strength of Patent barriers exist?	Valid active patents are NOT being worked in India (directly or via licensees) (Yes- 1; No-0)	Quantity being made available in India is NOT enough to meet Indian needs and affordable (Yes-1; No-0)	There are Indian manufacturers capable of (already making or prepared to) making this drug (Yes- 1; No-0)	Will Govt action be needed to provide FTO to Indian manufacturers (if drug proven important)?	SCORE: DRUG POTENTIAL (taken from Heat map - Drug Potential)	With current info available on drug, is it worthwhile for the GoI to take action to provide FTO for Indian manufacturers?	Drug candidate
Chloroquine	0%	NA	NA	NA	0%	54%	None reqd	Chloroquine
Hydroxychloroquine	0%	NA	NA	NA	0%	54%	None reqd	Hydroxychloroquine
Remdesivir	100%	1	1	1	100%	Awaiting CT data	Await CT data	Remdesivir
Lopinavir/Ritonavir	0%	NA	NA	NA	0%	34%	None reqd	Lopinavir/Ritonavir
Favipiravir	50%	1	1	1	100%	73%	36%	Favipiravir
Baloxavir Marboxil	100%	1	1	1	100%	Awaiting CT data	Await CT data	Baloxavir Marboxil
Darunavir	0%	NA	NA	NA	0%	34%	None reqd	Darunavir
Ribavirin + IFN beta	0%	NA	NA	NA	0%	Awaiting CT data	None reqd	Ribavirin + IFN beta
Galidesivir	0%	NA	NA	NA	0%	Awaiting CT data	None reqd	Galidesivir
Oseltamivir	0%	NA	NA	NA	0%	34%	None reqd	Oseltamivir
Umifenovir	0%	NA	NA	NA	0%	42%	None reqd	Umifenovir
Camostat mesylate	0%	NA	NA	NA	0%	Awaiting CT data	None reqd	Camostat mesylate
Ruxolitinib	100%	0	1	1	67%	Awaiting CT data	Await CT data	Ruxolitinib
Interferon beta	0%	NA	NA	NA	0%	Awaiting CT data	None reqd	Interferon beta
Tocilizumab	0%	NA	NA	NA	0%	73%	None reqd	Tocilizumab
Ustekinumab	100%	1	1	1	100%	Awaiting CT data	Await CT data	Ustekinumab
Nigericin	0%	NA	NA	NA	0%	Awaiting CT data	None reqd	Nigericin
Teicoplanin	0%	NA	NA	NA	0%	Awaiting CT data	None reqd	Teicoplanin
Ivermectin	0%	NA	NA	NA	0%	Awaiting CT data	None reqd	Ivermectin

Source: TFORD-COVID19-India (c) Venture Center, 2020



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Summary of Clinical Trials (Interventional) in India

(c) Venture Center, Pune, India (2020)

Owner Kirtree Wani

Last update: 9 May 2020

Table 1: CTs by intervention (sorted by number of trials)

Drug	No of trials - Prophylactic	No of trials - treatment	Total number of trials
Homeopathic	1	6	7
Ayurvedic	4	3	7
Convalescent Plasma	0	4	4
BCG Vaccine	2	1	3
Hydroxychloroquine	1	1	2
Chloroquine	0	2	2
Ayurvedic + Homeopathic	1	0	1
Remdesvir, Chloroquine, Hydroxychloroquine, Lopinavir/Ritonavir or +IFN	0	1	1
Hydroxychloroquine, Ciclesonide, Ivermectin	0	1	1
Imatinib	0	1	1
Itolizumab	1	0	1
Mw (Sepsivac)	0	1	1
Ivermectin	0	1	1
Povidone Iodine	0	1	1
Niclosamide	1	0	1
TOTAL	11	23	34

Table 2: CTs by start date

Start date	Number of trials
March 2020	0
April 2020	14
May 2020	20
TOTAL	34

Table 3: CTs by expected end date

End date	Number of trials
May 2020	0
June 2020	2
July 2020	6
Aug 2020	8
Oct 2020	6
Nov 2020	4
Jan 2021	1
Apr 2021	3
May 2021	4
TOTAL	34

Table 4: CTs by states (sorted by study size)

State	Number of trials	Cumulative size
DELHI	8	11762
ORISSA, MAHARASHTRA, ANDHRA PRADESH, HARYANA	1	5946
PONDICHERRY	1	1826
RAJASTHAN, TAMIL NADU, MADHYA PRADESH, MAHARASHTRA	1	1500
ANDHRA PRADESH	2	1296
GUJARAT, MAHARASHTRA, RAJASTHAN	1	600
KERALA	1	500
RAJASTHAN, GUJARAT	1	452
MAHARASHTRA	5	390
UTTAR PRADESH, DELHI	1	300
UTTAR PRADESH	3	300
HARYANA	2	120
KARNATAKA, UTTAR PRADESH, GUJARAT	1	112
KARNATAKA	3	72
MADHYA PRADESH, DELHI, CHANDIGARH	1	40
DELHI, KARNATAKA, MAHARASHTRA	1	30
GUJARAT	1	30
TOTAL	34	25276

Data from TFORD-COVID19-India (c) Venture Center, Pune

Website: www.nclinnovations.org/covid19/



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Priority Drugs for Clinical Trials

Drug	Purpose	Indian sources
Favipiravir	Reduce viral load in patients with moderate disease	Strides, Glenmark, Cipla@#
Remdesivir	Reduce viral load in moderate/severe disease	Cipla, Hetero, Jubilant, Mylan, Laxai@#
Umifenovir	1. For Post Exposure Prophylaxis in high risk individuals 2. Reduce viral load in mild/moderate disease	Laxai@#
Tocilizumab	Reduce hyperinflammation in severe disease	Cipla
Baricitinib	Reduce hyperinflammation in severe disease	Lilly India, Hetero, Cipla
Sepsivac/Mw	Reduce hyperinflammation in moderate/severe disease	Cadila@#
Famotidine	Reduce hyperinflammation in moderate/ severe disease	Dr Reddy's, IPCA, Cadila, Alembic and several others
Hydroxychloroquine + Azithromycin	Reduce viral load and inflammation in patients with mild/moderate disease	IPCA@, Torrent@, Cadila@, Laxai#

@ -- indigenous; # -- CSIR (GoI) technology

Date 13 May 2020



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Visibility



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The Principal Scientific Advisor to the GoI, Dr K VijayRaghavan, has constituted a S&T Core Group on COVID19.

- SUPPORT: A2K+ PROGRAM OF
DSIR -



DSIR
DEPARTMENT OF SCIENTIFIC AND
INDUSTRIAL RESEARCH

- DISCUSSION FORUM -

(5 April 2020) Leads for a translation ecosystem

(5 April 2020) Front line clinicians — tell us what works and does not?

(5 April 2020) Suggest your treatment strategies/ drug combinations

<https://nclinnovations.org/covid19/>



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TASK FORCE ON REPURPOSING OF DRUGS FOR COVID19

CHARTING THE PATH FOR INDIA

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RESOURCES

Information resources and records:

(Note: Public view documents are free to use and download under the [Creative Commons Attribution- Non Commercial – ShareAlike license](#). Some resources are restricted to only Coordinators, Nerve Center Team, Advisory Group)

- Molecule Briefs
 - With ongoing clinical trials
 - [Molecule Brief 1: Chloroquine](#) (Ver 30 March 2020)
 - [Molecule Brief 2: Hydroxychloroquine](#) (Ver 30 March 2020; Updated 5 April 2020)
 - [Molecule Brief 3: Remdesivir](#) (Ver 30 March 2020)
 - [Molecule Brief 4: Lopinavir/Ritonavir](#) (Ver 30 March 2020)
 - [Molecule Brief 5: Favipiravir](#) (Ver 30 March 2020)
 - [Molecule Brief 6: Baloxavir Marboxil](#) (Ver 30 March 2020)
 - [Molecule Brief 7: Darunavir](#) (Ver 12 April 2020)
 - [Molecule Brief 8: Ribavarin + IFN-beta](#) (Ver 12 April 2020)
 - [Molecule Brief 10: Oseltamivir](#) (Ver 12 April 2020)

<https://nclinnovations.org/covid19/resources/>



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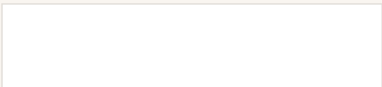


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DRUGS MONITOR
Tracking drugs for COVID19

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Recent Posts



(12 May 2020) Tocilizumab- onset to tocilizumab administration may be critical to patient recovery

🕒 MAY 13, 2020

(12 May 2020) Tocilizumab- onset to tocilizumab administration may be critical to patient recovery Early outcomes of tocilizumab in adults hospitalized with severe COVID-19 – 2 SUBTITLE: An initial report from

<http://nclinnovations.org/covid19monitor/>



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Social media handles:

Twitter: <https://twitter.com/TFORDCOVID19>

Linkedin: <https://www.linkedin.com/in/tford-covid19/>





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