

**Lessons learned  
on the  
management of  
ventilators at  
national level**



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## COVID-19 TREATMENT

- INCREASE NUMBER ICU BEDS
- INCREASE NEEDS VENTILATORS (invasive)
- INCREASE NEEDS: VENTILATION THERAPY. CPAP/BIPAP

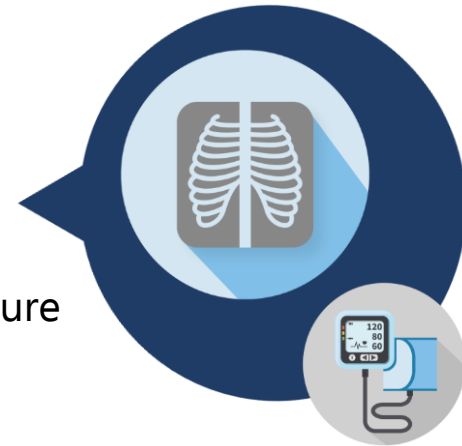


## PLANIFICATION IN 3 STEPS



### 1. Industrial NETWORK

- Increase current national manufacture capacity.
- Modify current designs. Anesthesia to ventilator



### 2. National derogations. According Medical Devices Directives and National legislation



### 3. Clinical investigations. Prototypes mechanical ventilators



## INDUSTRIAL NETWORK



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Main objective: Improve national industry. Ventilators.  
Collaboration. Ministry of Industry



### **Increase manufacturing capacity**

- Identified national manufacturers
- Check manufacturing capacity
- Ventilators per week: from 10 to 100

### **Modify current designs. Anaesthesia to ventilator**

- Two manufacturers modified anaesthesia equipment to ventilators



## NATIONAL DEROGATIONS



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According with medical Devices Directives and national legislation

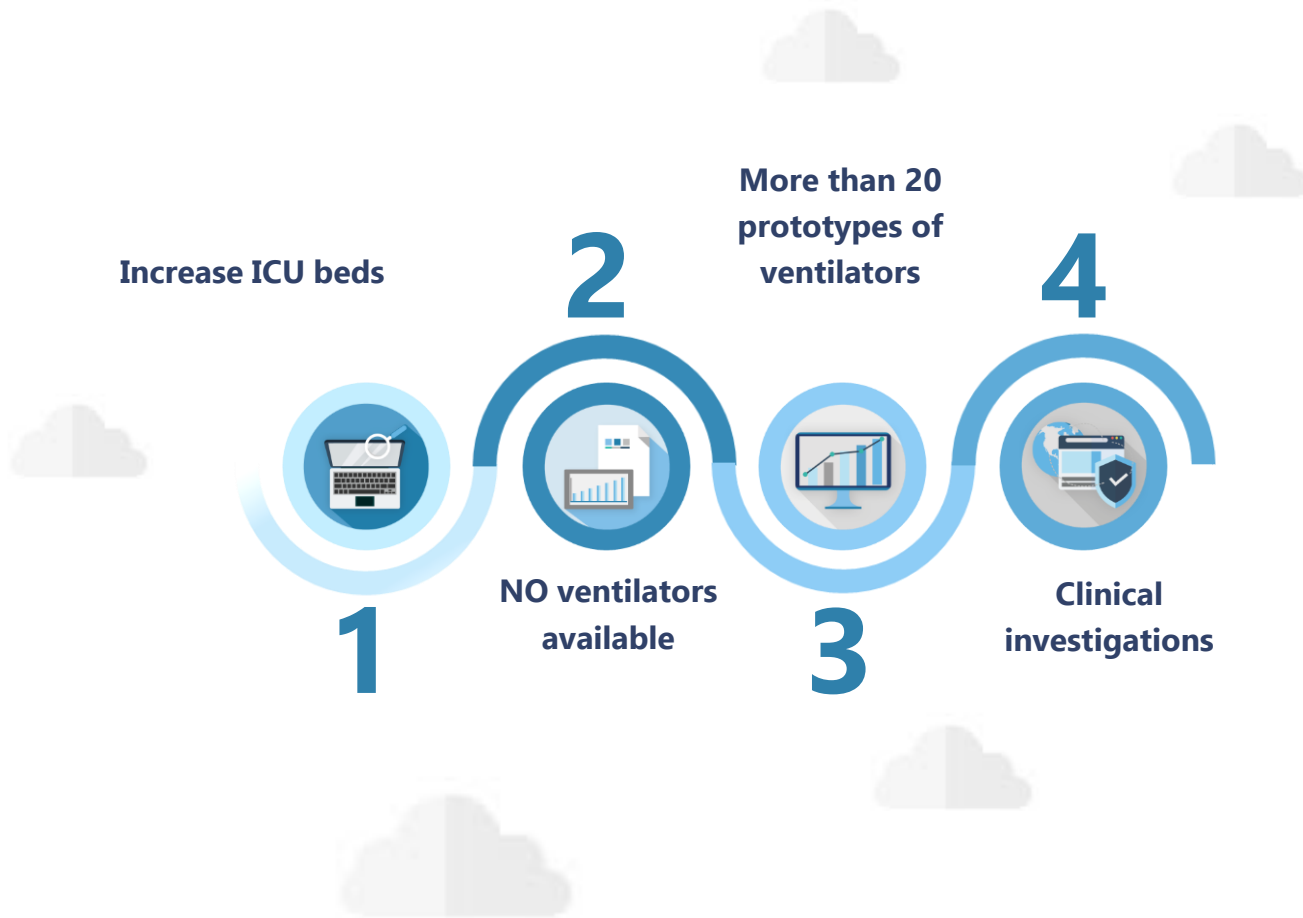


- **VENTILATORS.**
  - Approved by other legislations (FDA, Health Canada, TGA, etc)
  - 3 national derogations
- **CPAP/BIPAPs**
  - 3D piece to connect CE medical devices
  - 3 national derogations.
- **OXYGEN CONCENTRATOR**
  - 1 national derogation



## CLINICAL INVESTIGATIONS







## CLINICAL INVESTIGATIONS. VENTILATORS PROTOTYPE

9 CLINICAL INVESTIGATIONS APPROVED. ONLY IF NO ALTERNATIVE AVAILABLE

- 7 VENTILATORS
- 2 CPAPs

USED IN 1 OR 2 PATIENTS PER CLINICAL INVESTIGATION



### • CHECK TECHNICAL DATA & TESTs.

- Artificial lung test
- Preclinical test: Test conducted in animal model
- Test electrical safety, electromagnetic compatibility, etc.
- **Accredited laboratories**
- risk analysis, design, equivalence similar devices, etc

### STRICT INCLUSION CRITERIA

- Only COVID patients
- Need ventilation treatment
- No CE marked ventilator available



## LESSONS LEARNED

## Lessons learned

- KNOW NEEDS
- PREPAREDNESS
- RAPID RESPONSE



Balance  
Legislations vs Flexibility



Improve  
Innovation  
EU manufacturers



All initiatives not  
adequate



Knowledge of needs

## IMPORTANT:

- Technical services
- Replacements



# THANKS!

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