# Comorbidities Management Working Group

Liver Forum, Paris, April 10th 2018

# Management of comorbidities in NASH trials

- Provide a broad and consensual assessment of comorbidities that are relevant for NASH clinical trial endpoints and their management prior and during NASH trials

- *Ad-hoc* Comorbidity Management Working Group
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# Proposed items - 1

- ***Short description of comorbidities & their impact on natural history***
  - Diabetes, dyslipidemia, OSA, nephropathy, CAD, HTN, PCOS, early atherosclerosis…
  - To what extent a decompensation/worsening of the comorbidities impacts on the severity of liver damage.
- ***Trial conduct:***
  - Screening strategies and tools for comorbidities (which test for renal function?)
  - Metabolically stable concept
  - Inclusion cirteria (ranges BMI, HBA1c, Tygs…)
  - Stability in cardiometab drugs before randomization (type, time, dose)
  - Forbidden drugs as they can afect endpoints (MoA dependent); other non CM drugs
  - Run-in period (rationale, indication, modalities)

# Proposed items – 2

- ***Optimal management of comorbidities :***
  - What needs to be done before inclusion in the trial?
  - Monitoring during trial
  - Management during trial
    - Reconciling supranational guidelines in global trials?
  - Impact on trial outcomes
  - (How to monitor diet and lifestyle changes ?)
- ***Alcohol as a comorbidity ?*** Monitoring ?
- ***Monitoring for cardiometabolic outcomes***
  - Monitoring ? Thresholds ?