I AM ALS Patient-Centric Trial Design (PaCTD) Rating for Theracurmin

I AM ALS Patient-Centric Trial Design (PaCTD)	Duke University Theracurmin	
Open Label Extension	Yes - the whole trial is OLE	1
Minimize placebo usage - 33% or less	No placebo	1
A side by side Expanded Access Program		1
Part 1 Total		**3**
Part 1 Rating-Seats at the Table		**0.6**
Consideration of disease heterogeneity: e.g., Cross-Over Design or Delayed Start Design	Yes	1
Use of scientifically supportable inclusion criteria, pre-defined subset analysis, re-randomization at trial conclusion to equalize outlier progressors between trial arms, or alternative controls (historical, algorithmic etc.)	Yes	1
Investigation of biomarker	Yes - microbiome compared to healthy controls	1
Independent Unblinded Review Panel that can communicate with FDA where substantial proof of “efficacy” emerges before end of trial		1
Part 2 Total		**4**
Part 2 Rating-Advancing Science Quickly		**0.3**
Use of Run-In Observation Period - 3 months not acceptable -1 month ideally	No	1
Use of novel methods: wearables, telemedicine visits, financial burden	Yes	1
Part 3 Total		**2**
Part 3 Rating-Patient-Friendly		**0.1**
Total Rating		**1**
x5		**5**
I AM ALS PaCTD 5-Star Rating:		**5-Star**