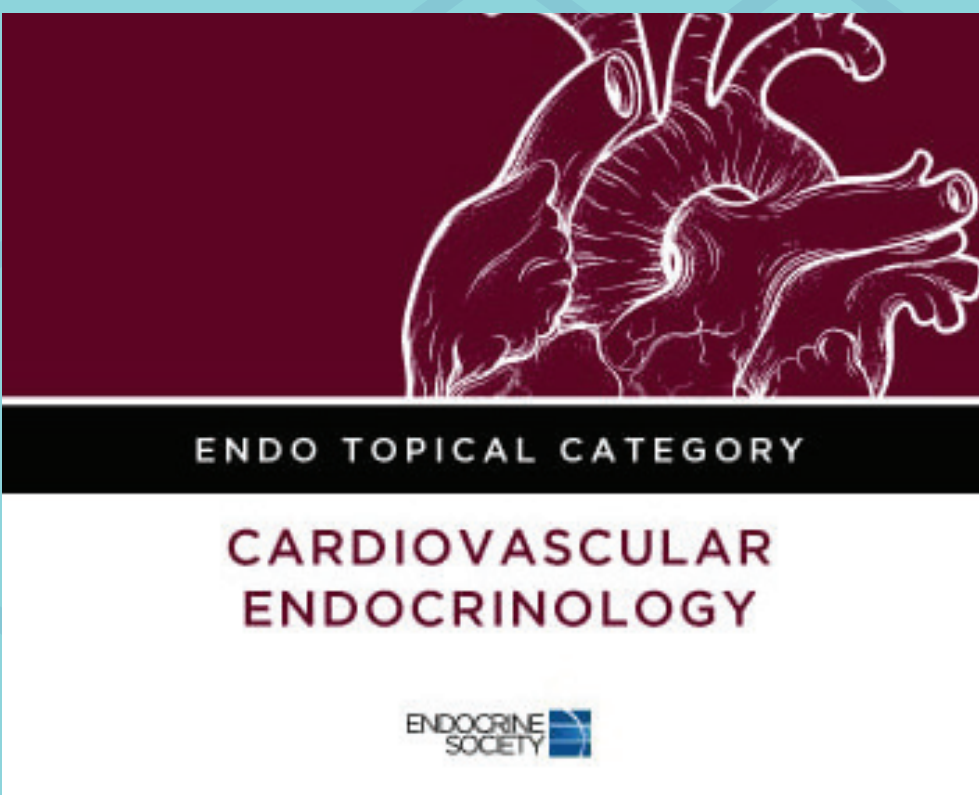




The Design of MOMENTUM: A Prospective Study of the Prevalence of Endogenous Hypercortisolism in Individuals With Resistant Hypertension

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SUMMARY AND CONCLUSIONS

- Previously, the prospective CATALYST study (N=1,057) found endogenous hypercortisolism in 24% of individuals with difficult-to-control type 2 diabetes and in 40% of the subgroup who also had systolic blood pressure ≥ 135 mmHg despite taking ≥ 3 blood pressure-lowering medications^{1,2}
 - These findings demonstrated a need to investigate the prevalence of endogenous hypercortisolism in a wider population with resistant hypertension
- The currently enrolling MOMENTUM study is designed to provide an estimate of endogenous hypercortisolism prevalence and its associated clinical characteristics in a US population of individuals with resistant hypertension
- It is anticipated that the data from MOMENTUM will expand our understanding of the association between endogenous hypercortisolism and resistant hypertension

BACKGROUND

- Affecting nearly 50% of adults, hypertension (HTN) is one of the most common disorders in the United States³
- Despite the availability of multiple medications, resistant hypertension (rHTN) occurs in ~10–20% of individuals treated for HTN⁴
- Endogenous hypercortisolism (eHC) may contribute to rHTN through multiple, well-understood physiologic mechanisms, including metabolic, vascular, and cardiac alterations⁵
- However, screening for eHC is low due to its perceived rarity and the perception that screening is challenging^{6,7}
- The prevalence of eHC in individuals with rHTN in the United States is currently unknown
 - Findings from the recent CATALYST study, the largest prospective study assessing eHC prevalence in >1,000 individuals with difficult-to-control type 2 diabetes,¹ demonstrated that 40% of the participant subgroup who also had systolic blood pressure (BP) ≥ 135 mmHg despite taking ≥ 3 BP-lowering medications had eHC²
- This finding also showed a need to investigate eHC prevalence in individuals with rHTN with and without diabetes
 - CATALYST also demonstrated that in a population that excluded common causes of false-positive results, eHC screening could consist of a 1-mg overnight dexamethasone suppression test (DST), which is readily performed in clinical practice¹
- The ongoing MOMENTUM study (NCT06829537) is the first large, prospective US study to examine the prevalence of eHC in individuals with rHTN

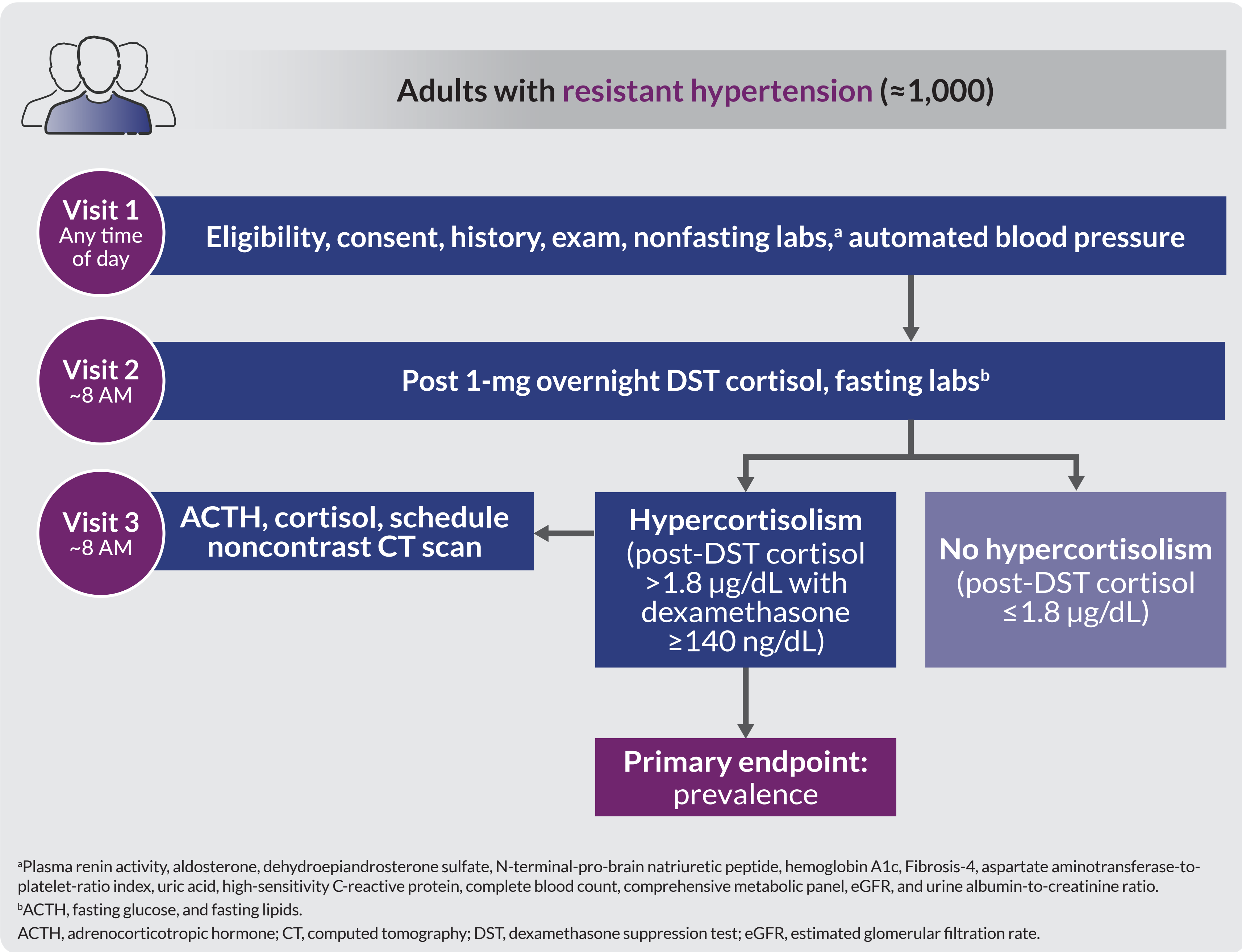


OBJECTIVES

- The MOMENTUM study's primary objective is to assess the prevalence of eHC in individuals with rHTN
- Secondary objectives include evaluating:
 - Clinical and laboratory characteristics that increase the likelihood of eHC
 - The proportion of individuals with markers of hyperaldosteronism and other causes of HTN
 - The percentage of individuals with eHC and rHTN who have abnormal adrenal imaging
 - Clinical and laboratory characteristics of individuals with and without abnormal adrenal imaging
- Exploratory objectives include:
 - Percentage and clinical and laboratory characteristics of individuals with post-DST cortisol 1.2–1.8 $\mu\text{g/dL}$ and <1.2 $\mu\text{g/dL}$
 - Performance of a complete blood count to predict the results of the DST based on subsets of white blood cells
 - Whether the degree of cortisol elevation post-DST has predictive value for comorbidity severity and/or presence and size of adrenal nodules

METHODS

Figure 1. Flow of Participants in the MOMENTUM Study



^aPlasma renin activity, aldosterone, dehydroepiandrosterone sulfate, N-terminal-pro-brain natriuretic peptide, hemoglobin A1c, Fibrosis-4, aspartate aminotransferase-to-platelet-ratio index, uric acid, high-sensitivity C-reactive protein, complete blood count, comprehensive metabolic panel, eGFR, and urine albumin-to-creatinine ratio.
^aACTH, fasting glucose, and fasting lipids.
ACTH, adrenocorticotropic hormone; CT, computed tomography; DST, dexamethasone suppression test; eGFR, estimated glomerular filtration rate.

Inclusion and Exclusion Criteria

- MOMENTUM is enrolling male and female individuals aged ≥ 18 years with rHTN (Table 1)
- Major exclusion criteria include investigator-determined white coat HTN, nonadherence to BP medications, and individuals in whom DST results may be difficult to interpret

Table 1. MOMENTUM Study Inclusion and Exclusion Criteria

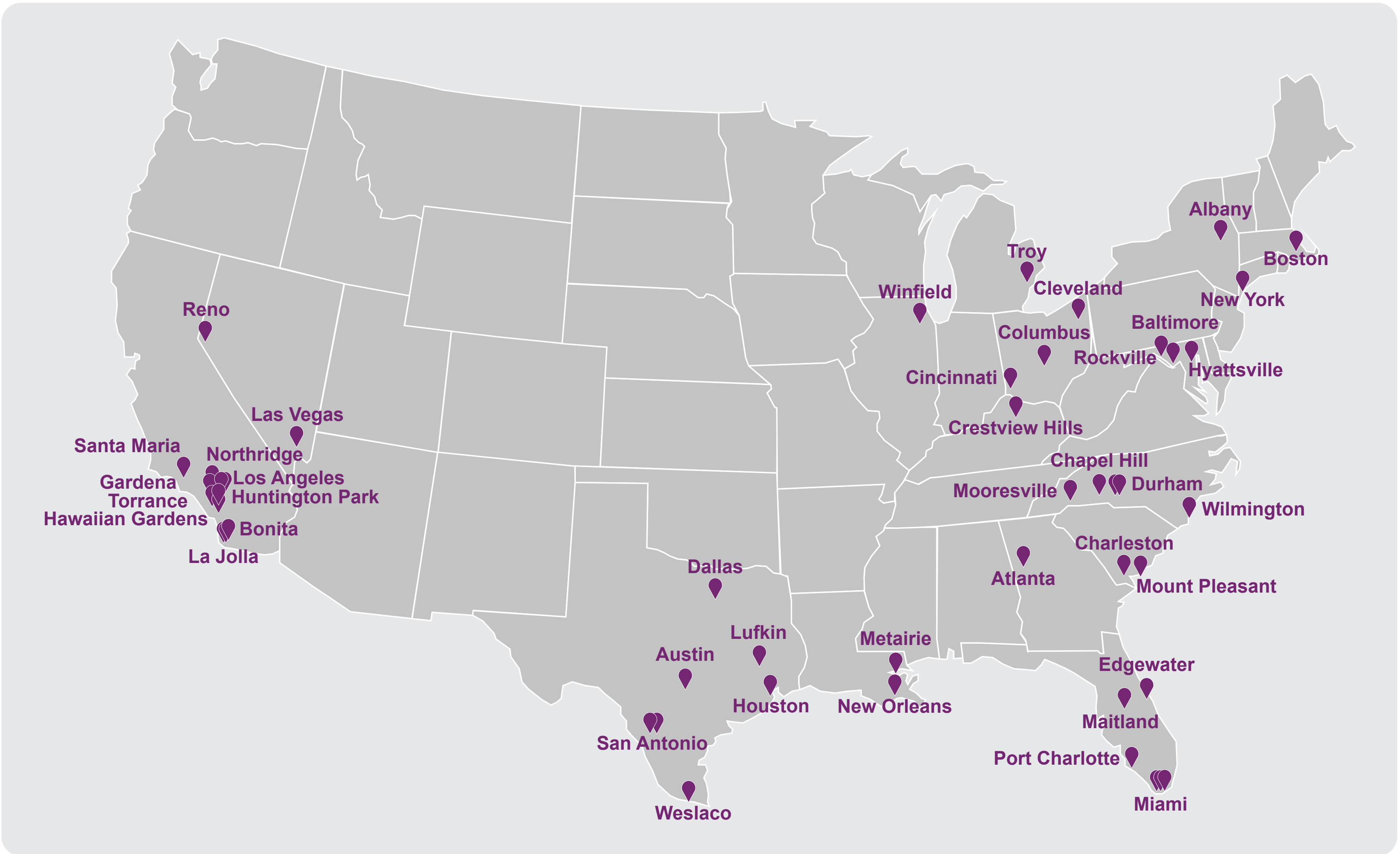
Inclusion criteria	- Aged ≥ 18 years - Resistant hypertension defined according to American Heart Association criteria
Exclusion criteria	- Investigator-determined white coat hypertension (ie, elevated blood pressure in the office only) - Investigator-determined nonadherence to blood pressure medications - Systemic glucocorticoid medications exposure (excluding inhalers or topical) ≤ 3 months of screening - Historical eGFR <30 mL/min/1.73 m² - Investigator-determined: - Severe untreated sleep apnea - Excessive alcohol consumption (eg, >14 units/week for male, >7 units/week for female) - Severe acute psychiatric, medical, or surgical illness - Pregnant or lactating - History of congenital adrenal hyperplasia - Diagnosed with endogenous hypercortisolism and/or has used or plans to use endogenous hypercortisolism medications^a - History of hypersensitivity or severe reaction to dexamethasone - Patients on OCPs who are unable to stop for ≥ 6 weeks prior to screening

^aMifepristone, metyrapone, osilodrostat, ketoconazole, fluconazole, aminoglutethimide, etomidate, octreotide, lanreotide, pasireotide, long-acting octreotide, or pasireotide. DST, dexamethasone suppression test; eGFR, estimated glomerular filtration rate; OCP, oral contraceptive pills.

Study Sites

- The study is being conducted at 48 sites in the United States (Figure 2), and enrollment is currently ongoing

Figure 2. MOMENTUM Study Sites



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Author Disclosures

Potential conflicts of interest may exist. Refer to the Meeting App.