



**Validation**Institute

# 2022 Validation Report

**Review for: Virta Health**

**Validation Achieved: Level 1 - Savings**

**Valid through: October 2022**



# Company Profile

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|                           |  |
|---------------------------|--|
| <b>Category:</b>          | Disease Management   |
| <b>Website:</b>           | <a href="http://www.virtahealth.com">www.virtahealth.com</a> |
| <b>Public or Private:</b> | Private  |
| <b>Year Established:</b>  | 2014   |
| <b>CEO:</b>               | Sami Inkinen   |
| <b>Company contact:</b>   | support@virtahealth.com                                      |



## Description:

**Virta Health** is the first clinically-proven treatment to safely and sustainably reverse type 2 diabetes and other chronic metabolic diseases without the use of medications or surgery. **Virta Health's** innovations in nutritional biochemistry, data science and digital tools combined with clinical expertise are shifting the diabetes treatment paradigm from management to reversal. **Virta Health's** mission is to reverse type 2 diabetes in 100 million people by 2025.





# Claim Assertion for Validation

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Virta Health delivers diabetes prescription drug cost savings of \$186 PMPM in year 1 and \$280 PMPM in year 2.





# Method / Calculation / Examples

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Virta Health offers a treatment for type 2 diabetes reversal that utilizes a combination of nutritional therapy based on carbohydrate restriction, as well as a novel telemedicine approach called “continuous remote care.” Multiple peer-reviewed studies have shown that patients receiving this treatment see significant improvements in HbA1c while simultaneously reducing or eliminating the need for glucose-lowering diabetes drugs.

*Virta Health partnered with Indiana University Health on a parallel arm, outpatient clinical trial, with 262 patients enrolled in Virta Health receiving continuous care intervention, and 87 receiving usual care[1]. Primary outcomes were retention, glycemic outcomes, and weight changes over 2 years. Retention over two years was 78% in the Usual Care group and 74% in the Virta Health intervention (Table 1). This is considered by the Validation Institute to be comparable.*

Participants were recruited from two clinics. One offered enrollment in Virta Health and one offered enrollment in usual care, where patients could select to participate or not, while all are included in the outcomes other than those lost to follow up. All signed informed consent to participate. One can consider this trial design as similar to a two-site cluster randomized trial, which is viewed as a “Gold Standard” by the Validation Institute. An example of another valid study done as a cluster randomization is here.



# Method / Calculation / Examples

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|                                  | Baseline | 1-year | 2-year |
|----------------------------------|----------|--------|--------|
| <b>Virta Health intervention</b> |          |        |        |
| n                                | 262      | 218    | 194    |
| Retention                        |          | 83%    | 74%    |
| <b>Usual Care (UC)</b>           |          |        |        |
| n                                | 87       | 78     | 68     |
| Retention                        |          | 90%    | 78%    |

Table 1. Study Size and Retention Rate over Two Years

The number of patients on each diabetes drug class was measured at baseline, at one year, and at two years in each group. For example, at baseline, approximately 57% of the cluster offered Virta Health were on glucose-lowering diabetes drugs (excluding metformin), compared to 67% of patients in the cluster that consented but was offered Usual Care. Among those who completed two years of the trial, only 27% of Virta Health patients were on diabetes drugs other than metformin, compared to 79% of Usual Care patients (Table 2). As mentioned above, retention over two years was 78% in the Usual Care group and 74% in the Virta Health intervention. (This difference is considered negligible and aligns with the expectation that the Virta Health treatment requires more commitment than usual care).



# Method / Calculation / Examples

|   | Baseline     |            | 1-year       |            | 2-year       |            |
|---|--------------|------------|--------------|------------|--------------|------------|
|   | Virta Health | Usual Care | Virta Health | Usual Care | Virta Health | Usual Care |
| <b>Any diabetes drug, excluding Metformin</b> | <b>57%</b>   | <b>67%</b> | <b>28%</b>   | <b>76%</b> | <b>27%</b>   | <b>79%</b> |
| Sulfonylurea                                  | 24%          | 24%        | 0%           | 26%        | 0%           | 29%        |
| Insulin                                       | 30%          | 46%        | 15%          | 51%        | 11%          | 55%        |
| Thiazolidinedione                             | 2%           | 1%         | 1%           | 1%         | 3%           | 7%         |
| SGLT-2  | 10%          | 15%        | 1%           | 17%        | 3%           | 14%        |
| DPP-4   | 10%          | 8%         | 6%           | 12%        | 7%           | 9%         |
| GLP-1   | 13%          | 16%        | 15%          | 21%        | 11%          | 28%        |
| Metformin                                     | 71%          | 61%        | 64%          | 60%        | 64%          | 64%        |

Table 2. Percentage of Population Segment Utilizing Diabetes Drugs





# Method / Calculation / Examples

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To estimate the cost of diabetes drugs, we studied market data from a variety of sources[2] and made assumptions for a typical commercial payor's allowed cost of a one-month supply for each diabetes medication class as illustrated in Table 3 below. We also constructed a dynamic model that allows users to enter their own negotiated price for drugs, if needed, and as required by the Validation Institute.

| <b>Diabetes Drug</b> | <b>Allowed Cost for 1 Month Supply</b> |
|----------------------|--|
| Sulfonylurea         | \$15                                   |
| Insulin              | \$420                                  |
| Thiazolidinedione    | \$15                                   |
| SGLT-2               | \$330                                  |
| DPP-4                | \$340                                  |
| GLP-1                | \$480                                  |
| Metformin            | \$10                                   |

Table 3. Allowed Cost of Drugs to Payer for One Month Supply



# Method / Calculation / Examples

We constructed a difference-in-differences savings estimate to compare the per member per month (PMPM) costs between Virta Health patients and Usual Care patients at 1 year and at 2 years (Table 4). This analysis utilized both the drug utilization data as well as the cost per drug data to determine average monthly costs for each cohort, compared to the baseline values on a PMPM basis (Table 5). The cost per drug was trended at 8.8% annually to reflect the approximate increase of diabetic drug costs over time. The annual trend of 8.8% is derived from the total health care cost of diabetes patients published by the ADA from 2012 to 2017, in Economic Costs of Diabetes in the U.S. in 2017. (Changes in the assumption of annual trend would not materially change the savings estimate.)

|                    | Usual Care      |                 |                 | Virta Health    |                 |                 | Difference       |                   |                   |
|--------------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|------------------|-------------------|-------------------|
|                    | Baseline        | 1-year          | 2-year          | Baseline        | 1-year          | 2-year          | Baseline         | 1-year            | 2-year            |
| Sulfonylurea       | \$3.62          | \$4.18          | \$5.20          | \$3.56          | \$0.00          | \$0.00          | (\$0.06)         | (\$4.18)          | (\$5.20)          |
| Insulin            | \$193.20        | \$234.42        | \$274.44        | \$125.16        | \$67.17         | \$56.18         | (\$68.04)        | (\$167.25)        | (\$218.26)        |
| Thiazolidinedione  | \$0.18          | \$0.21          | \$1.23          | \$0.23          | \$0.08          | \$0.46          | \$0.05           | (\$0.13)          | (\$0.76)          |
| SGLT-2             | \$49.17         | \$59.96         | \$53.91         | \$33.99         | \$3.23          | \$12.11         | (\$15.18)        | (\$56.73)         | (\$41.80)         |
| DPP-4              | \$27.54         | \$42.54         | \$34.61         | \$33.66         | \$23.67         | \$26.97         | \$6.12           | (\$18.87)         | (\$7.65)          |
| GLP-1              | \$77.28         | \$107.06        | \$156.82        | \$64.32         | \$78.86         | \$61.37         | (\$12.96)        | (\$28.20)         | (\$95.46)         |
| Metformin          | \$6.09          | \$6.56          | \$7.55          | \$7.14          | \$6.98          | \$7.56          | \$1.05           | \$0.42            | \$0.01            |
| <b>Grand Total</b> | <b>\$357.08</b> | <b>\$454.93</b> | <b>\$533.76</b> | <b>\$268.05</b> | <b>\$180.00</b> | <b>\$164.65</b> | <b>(\$89.03)</b> | <b>(\$274.93)</b> | <b>(\$369.12)</b> |

Table 4. Difference in Diabetes Drug Cost Between Virta Health and Usual Care at Baseline, 1 Year, 2 Years





# Method / Calculation / Examples

| Year 1                                    | Year 2                                    |
|---|---|
| \$185.90 PMPM                             | \$280.09 PMPM                             |
| = 1 year difference - Baseline difference | = 2 year difference - Baseline difference |
| = \$274.93 - \$89.03                      | = \$369.12 - \$89.03                      |

Table 5. Estimated PMPM Savings of Virta Health intervention, Utilizing a Difference-in-Differences Calculation

Multiple additional studies of Virta Health have been reported, including among Virta Health’s commercial book of business—validating “real world” outcomes—as well as among a population of veterans treated at the Veterans Health Administration[3]. The VHA study, which employed a quasi-experimental waitlist design, found a medication reduction of 34.5% after over 5 months. (These data points are added as support for the valid study results. The VHA study’s waitlist control would be considered a Gold Standard if the power is high enough, but the more typical and practical and ERISA-compliant commercial participants-vs-non-participants study design can overstate savings.)





## Findings & Validation

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Virta Health's intervention showed diabetes drug cost savings of \$185.90 PMPM in year 1 and \$280.09 PMPM in year 2. Other potential sources of savings for Virta Health—e.g., related to medical cost savings stemming from improved A1c or weight loss—were beyond the scope of this analysis.





# Limitations

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Unlike in a participants-vs-non-participants comparison or a comparison to history of members, there is no “limitation” that there could be unknowable differences between the cohorts due to willingness to participate. The material limitations are:

- The sample size is smaller than ideal. A larger sample size would have a tighter confidence interval but there is no reason to think that a larger sample would have different results solely by dint of its size;
- There is no guarantee that future results in any given organization will mirror these results.



## Works Cited

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- [1] Athinarayanan SJ, et al. Long-Term Effects of a Novel Continuous Remote Care Intervention Including Nutritional Ketosis for the Management of Type 2 Diabetes: A 2-year Non-randomized Clinical Trial. *Frontiers in Endocrinology*. 2019; 10:348.
- [2] Sources include: GoodRx.com, Insulin Cost and Pricing Trends published by American Action Forum, Comparative Effectiveness Review Summary Guides for Consumers, and expert interviews. For diabetes drugs with typical monthly cost of exceeding \$50, a 40% discount is assumed to simulate discounts and rebates a payer may receive. Costs are normalized to 2022 where needed using annual trend of 8.8%.
- [3] Strombotne, KL, Lum, J, Ndugga, NJ, et al. Effectiveness of a ketogenic diet and virtual coaching intervention for patients with diabetes: A difference-in-differences analysis. *Diabetes Obes Metab*. 2021; 23( 12): 2643- 2650.



# Validation and Credibility Guarantee

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**Virta Health's intervention** achieved level 1 validation for Savings. Validation Institute is willing to provide up to a \$25,000 guarantee as part of their Credibility Guarantee Program. To learn more, visit <https://validationinstitute.com/credibility-guarantee/>.

## Level 1 – Savings

Can reduce health care spending per case/participant or for the plan/purchaser overall.

## Level 2 – Outcomes

Product/solution has measurably moved the needle on an outcome (risk, hba1c, events, employee retention, etc.) of importance.

## Level 3 – Metrics

Credible sources and valid assumptions create a reasonable estimate of a program's impact.

## Level 4 - Contractual Integrity

Vendor is willing to put a part of their fees "at risk" as a guarantee.





**Validation Expiration: October 2022**

# CERTIFICATE OF VALIDATION

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**Applicant:**

**Virta Health**

501 Folsom St.

San Francisco, California, 94105

**Product:**

Virta Health intervention

**Claim:**

Virta Health delivers diabetes prescription drug cost savings of \$186 PMPM in year 1 and \$280 PMPM in year 2.

**Validation Achieved:**

**Level 1 - Validated for Savings**

**Validation Award Date:**

**February 2022**

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**Al Lewis**

**Senior Advisor**

**Validation Institute**

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**Benny DiCecca**

**Chief Executive Officer**

**Validation Institute**





# About Validation Institute

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**Validation Institute** is a professional community that advocates for organizations and approaches that deliver better health value - stronger health outcomes at lower cost. We connect, train, and certify health care purchasers, and we validate and connect providers delivering superior results. Founded in 2014, the mission of the organization has consistently been to help provide transparency to buyers of health care.

